	FDA Fotoklick od Dkommoodlovic Ologo (FDO) Tout Dkmood
	FDA Established Pharmacologic Class (EPC) Text Phrase
	PLR regulations require that the following statement is included in the Highlights
	Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
Active Meiety Name	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
Active Moiety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
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	Use in the Highlights" MAPP 7400.13.
2.2'-dithiobisbenzothiazole	standardized chemical allergen
2-mercaptobenzothiazole	standardized chemical allergen
2-mercaptoethanesulfonic acid	cytoprotective agent
4-hydroxybutanoic acid	central nervous system depressant
abacavir	HIV nucleoside analog reverse transcriptase inhibitors (HIV NRTI)
abatacept	selective T cell costimulation modulator
abies balsamea pollen	non-standardized pollen allergenic extract
abies concolor pollen	non-standardized pollen allergenic extract
abies grandis pollen	non-standardized pollen allergenic extract
abies procera pollen	non-standardized pollen allergenic extract
abiraterone	CYP17 inhibitor
acacia	non-standardized plant allergenic extract
acacia baileyana pollen	non-standardized pollen allergenic extract
acacia dealbata pollen	non-standardized pollen allergenic extract
acacia longifolia pollen	non-standardized pollen allergenic extract
acacia pollen	non-standardized pollen allergenic extract
acarbose	alpha glucosidase inhibitor
acebutolol	beta adrenergic blocker
acer macrophyllum pollen	non-standardized pollen allergenic extract
acer negundo pollen	non-standardized pollen allergenic extract
acer pseudoplatanus pollen	non-standardized pollen allergenic extract
acer rubrum pollen	non-standardized pollen allergenic extract
acer saccharinum pollen	non-standardized pollen allergenic extract
acer saccharum pollen	non-standardized pollen allergenic extract
acetazolamide	carbonic anhydrase inhibitor
acetohydroxamic acid	urease inhibitor

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acetylcholine	cholinergic agonist
acetylcysteine	mucolytic antidote for acetaminophen overdose
acetylcysteine	mucolytic antidote for acetaminophen overdose
acetylcysteine	mucolytic antidote for acetaminophen overdose
acheta domesticus	non-standardized insect allergenic extract
achillea millefolium pollen	non-standardized pollen allergenic extract
achnatherum coronatum pollen	non-standardized pollen allergenic extract
acitretin	retinoid
acremonium strictum	non-standardized fungal allergenic extract
acrivastine	histamine-1 (H1) receptor antagonist
acrothecium robustum	non-standardized fungal allergenic extract
acyclovir	nucleoside analog HSV DNA polymerase inhibitor / VZV DNA polymerase inhibitor
acyclovir	nucleoside analog HSV DNA polymerase inhibitor / VZV DNA polymerase inhibitor
acyclovir	nucleoside analog HSV DNA polymerase inhibitor / VZV DNA polymerase inhibitor
adalimumab	tumor necrosis factor (TNF) blocker
adapalene	retinoid
adefovir	HBV nucleoside analog reverse transcriptase inhibitor (HBV-NRTI)
adenosine	adenosine receptor agonist
aedes taeniorhynchus	non-standardized insect allergenic extract
aesculus hippocastanum pollen	non-standardized pollen allergenic extract
afatinib	kinase inhibitor
agalsidase beta	hydrolytic lysozomal neutral glycosphingolipid-specific enzyme
agave sisalana fiber	non-standardized plant fiber allergenic extract
agropyron cristatum pollen	non-standardized pollen allergenic extract
agropyron fragile pollen	non-standardized pollen allergenic extract
agrostis capillaris pollen	non-standardized pollen allergenic extract

	FDA Fatalital ad Disamasa alawia Olasa (FDO) Tant Disama
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agrostis gigantea pollen	non-standardized pollen allergenic extract
agrostis gigantea pollen	standardized pollen allergenic extract
agrostis stolonifera pollen	non-standardized pollen allergenic extract
ailanthus altissima pollen	non-standardized pollen allergenic extract
alanine	amino acid
albendazole	anthelmintic
albiglutide	GLP-1 receptor agonist
albizia julibrissin pollen	non-standardized pollen allergenic extract
albumin (human)	human serum albumin
albuterol	beta-2 adrenergic agonist
alclometasone	corticosteroid
aldesleukin	lymphocyte growth factor
alefacept	CD2-directed LFA-3/Fc fusion protein
alemtuzumab	CD52-directed cytolytic antibody
alendronic acid	bisphosphonate
alfentanil	opioid agonist
alfuzosin	alpha adrenergic blocker
alglucerase	hydrolytic lysozomal glucocerebroside-specific enzyme
alglucosidase alfa	hydrolytic lysozomal glycogen-specific enzyme
aliskiren	renin inhibitor
alitretinoin	retinoid
allenrolfea occidentalis pollen	non-standardized pollen allergenic extract
allocasuarina huegeliana pollen	non-standardized pollen allergenic extract
allopurinol	xanthine oxidase inhibitor
allspice	non-standardized food allergenic extract
allspice	non-standardized plant allergenic extract

	EDA F-(-LI'-LI DL
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almond	non-standardized food allergenic extract
almotriptan	serotonin 5-HT1B/1D receptor agonist (triptan)
alnus glutinosa bark	non-standardized plant allergenic extract
alnus incana subsp. rugosa pollen	non-standardized pollen allergenic extract
alnus incana subsp. tenuifolia pollen	non-standardized pollen allergenic extract
alnus rhombifolia pollen	non-standardized pollen allergenic extract
alnus rubra pollen	non-standardized pollen allergenic extract
alnus viridis subsp. sinuata pollen	non-standardized pollen allergenic extract
alopecurus arundinaceus pollen	non-standardized pollen allergenic extract
alopecurus pratensis pollen	non-standardized pollen allergenic extract
alosetron	serotonin-3 (5-HT3) receptor antagonist
alpha1-proteinase inhibitor human	human alpha-1 proteinase inhibitor
alpha-amylcinnamaldehyde	standardized chemical allergen
alpha-lactalbumin	non-standardized food allergenic extract
alprazolam	benzodiazepine
alprostadil	prostaglandin analog
alprostadil	prostaglandin E1 agonist
alternaria alternata	non-standardized fungal allergenic extract
alternaria solani	non-standardized fungal allergenic extract
altretamine	alkylating drug
alvimopan	opioid antagonist
alvimopan anhydrous	opioid antagonist
amantadine	influenza A M2 protein inhibitor
amaranthus albus pollen	non-standardized pollen allergenic extract
amaranthus blitoides pollen	non-standardized pollen allergenic extract
amaranthus hybridus pollen	non-standardized pollen allergenic extract

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amaranthus palmeri pollen	non-standardized pollen allergenic extract
amaranthus retroflexus pollen	non-standardized pollen allergenic extract
amaranthus spinosus pollen	non-standardized pollen allergenic extract
amaranthus tuberculatus pollen	non-standardized pollen allergenic extract
ambenonium	cholinesterase inhibitor
ambrisentan	endothelin receptor antagonist
ambrosia acanthicarpa pollen	non-standardized pollen allergenic extract
ambrosia ambrosioides pollen	non-standardized pollen allergenic extract
ambrosia artemisiifolia pollen	standardized pollen allergenic extract
ambrosia bidentata pollen	non-standardized pollen allergenic extract
ambrosia chamissonis pollen	non-standardized pollen allergenic extract
ambrosia confertiflora pollen	non-standardized pollen allergenic extract
ambrosia deltoidea pollen	non-standardized pollen allergenic extract
ambrosia dumosa pollen	non-standardized pollen allergenic extract
ambrosia monogyra pollen	non-standardized pollen allergenic extract
ambrosia psilostachya pollen	non-standardized pollen allergenic extract
ambrosia salsola pollen	non-standardized pollen allergenic extract
ambrosia tenuifolia pollen	non-standardized pollen allergenic extract
ambrosia tomentosa pollen	non-standardized pollen allergenic extract
ambrosia trifida pollen	non-standardized pollen allergenic extract
amcinonide	corticosteroid
american chestnut	non-standardized food allergenic extract
american chestnut	non-standardized plant allergenic extract
american gooseberry	non-standardized food allergenic extract
american gooseberry	non-standardized plant allergenic extract
american hazelnut	non-standardized food allergenic extract

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american hazelnut	non-standardized plant allergenic extract
american lobster	non-standardized food allergenic extract
amifostine	cytoprotective agent
amifostine anhydrous	cytoprotective agent
amikacin	aminoglycoside antibacterial
amiloride	potassium-sparing diuretic
amino acids	amino acid hypertonic solution
aminobenzoic acid	vitamin B complex member
aminocaproic acid	antifibrinolytic
aminoglutethimide	adrenal steroid synthesis inhibitor
aminolevulinic acid	porphyrin precursor
amiodarone	antiarrhythmic
amitriptyline	tricyclic antidepressant (TCA)
amlodipine	dihydropyridine calcium channel blocker
ammonia n-13	radioactive diagnostic agent
ammonium lactate	alpha hydroxy acid
ammophila arenaria pollen	non-standardized pollen allergenic extract
amoxapine	tricyclic antidepressant (TCA)
amoxicillin	penicillin class antibacterial
amoxicillin anhydrous	penicillin class antibacterial
amphetamine	central nervous system stimulant
amphiachyris dracunculoides pollen	non-standardized pollen allergenic extract
amphotericin b	lipid-based polyene antifungal
amphotericin b	polyene antifungal
ampicillin	penicillin class antibacterial
amprenavir	HIV protease inhibitor

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anagrelide	platelet-reducing agent
anakinra	interleukin-1 (IL-1) receptor antagonist
anas platyrhynchos feather	non-standardized feather allergenic extract
anastrozole	aromatase inhibitor
anhydrous citric acid	anti-coagulant
anhydrous citric acid	urinary calculi dissolution agent
anidulafungin	echinocandin antifungal
anise	non-standardized food allergenic extract
anise	non-standardized plant allergenic extract
anopheles quadrimaculatus	non-standardized insect allergenic extract
anser anser feather	non-standardized feather allergenic extract
anthemis arvensis pollen	non-standardized pollen allergenic extract
anthemis cotula pollen	non-standardized pollen allergenic extract
anthoxanthum odoratum pollen	standardized pollen allergenic extract
antihemophilic factor human	human antihemophilic factor
antihemophilic factor, human recombinant	human antihemophilic factor
anti-inhibitor coagulant complex	anti-inhibitory coagulant complex
antithrombin alfa	recombinant antithrombin
antivenin (latrodectus mactans) (equine)	antivenin
apiospora montagnei	non-standardized fungal allergenic extract
apis mellifera	standardized insect venom protein allergenic extract
apixaban	factor Xa inhibitor
apomorphine	dopaminergic agonist
apple	non-standardized food allergenic extract
apraclonidine	alpha adrenergic agonist

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apremilast	phosphodiesterase 4 inhibitor
aprepitant	substance P/neurokinin-1 (NK-1) receptor antagonist
apricot	non-standardized food allergenic extract
aprotinin	antifibrinolytic
arabica coffee bean	non-standardized food allergenic extract
arabica coffee bean	non-standardized plant allergenic extract
araucaria columnaris pollen	non-standardized pollen allergenic extract
arformoterol	beta-2 adrenergic agonist
argatroban	anti-coagulant
argatroban	direct thrombin inhibitor
aripiprazole	atypical antipsychotic
arrhenatherum elatius pollen	non-standardized pollen allergenic extract
artemether	antimalarial
artemisia absinthium pollen	non-standardized pollen allergenic extract
artemisia annua pollen	non-standardized pollen allergenic extract
artemisia biennis pollen	non-standardized pollen allergenic extract
artemisia californica pollen	non-standardized pollen allergenic extract
artemisia campestris pollen	non-standardized pollen allergenic extract
artemisia douglasiana pollen	non-standardized pollen allergenic extract
artemisia dracunculus pollen	non-standardized pollen allergenic extract
artemisia filifolia pollen	non-standardized pollen allergenic extract
artemisia frigida pollen	non-standardized pollen allergenic extract
artemisia ludoviciana pollen	non-standardized pollen allergenic extract
artemisia pycnocephala pollen	non-standardized pollen allergenic extract
artemisia suksdorfii pollen	non-standardized pollen allergenic extract
artemisia tridentata pollen	non-standardized pollen allergenic extract

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artemisia vulgaris pollen	non-standardized pollen allergenic extract
articaine	amide local anesthetic
artichoke	non-standardized food allergenic extract
artichoke	non-standardized plant allergenic extract
asenapine	atypical antipsychotic
asparaginase	asparagine-specific enzyme
asparagus	non-standardized food allergenic extract
aspergillus clavatus	non-standardized fungal allergenic extract
aspergillus flavipes	non-standardized fungal allergenic extract
aspergillus flavus	non-standardized fungal allergenic extract
aspergillus flavus var. oryzae protease	non-standardized fungal allergenic extract
aspergillus fumigatus	non-standardized fungal allergenic extract
aspergillus nidulans	non-standardized fungal allergenic extract
aspergillus niger var. niger	non-standardized fungal allergenic extract
aspergillus ochraceus	non-standardized fungal allergenic extract
aspergillus repens	non-standardized fungal allergenic extract
aspergillus restrictus	non-standardized fungal allergenic extract
aspergillus sydowii	non-standardized fungal allergenic extract
aspergillus terreus	non-standardized fungal allergenic extract
aspergillus ustus	non-standardized fungal allergenic extract
aspergillus versicolor	non-standardized fungal allergenic extract
aspirin	nonsteroidal anti-inflammatory drug
atazanavir	HIV protease inhibitor
atenolol	beta adrenergic blocker
atlantic cod	non-standardized food allergenic extract
atlantic halibut	non-standardized food allergenic extract

	EDA Establishad Dhamasadani's Olasa (EDO) Tant Dhamas
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atlantic mackerel	non-standardized food allergenic extract
atlantic salmon	non-standardized food allergenic extract
atomoxetine	selective norepeinephrine reuptake inhibitor
atorvastatin	HMG CoA-reductase inhibitor
atovaquone	antimalarial
atovaquone	antiprotozoal
atracurium	nondepolarizing neuromuscular blocker
atriplex argentea pollen	non-standardized pollen allergenic extract
atriplex canescens pollen	non-standardized pollen allergenic extract
atriplex confertifolia pollen	non-standardized pollen allergenic extract
atriplex lentiformis pollen	non-standardized pollen allergenic extract
atriplex linearis pollen	non-standardized pollen allergenic extract
atriplex pacifica pollen	non-standardized pollen allergenic extract
atriplex patula pollen	non-standardized pollen allergenic extract
atriplex polycarpa pollen	non-standardized pollen allergenic extract
atriplex rosea pollen	non-standardized pollen allergenic extract
atriplex serenana pollen	non-standardized pollen allergenic extract
atriplex wrightii pollen	non-standardized pollen allergenic extract
atropine	anticholinergic
atropine	muscarinic antagonist
aureobasidium pullulans var. pullutans	non-standardized fungal allergenic extract
autologous cultured chondrocytes	autologous cultured cell
avanafil	phosphodiesterase 5 (PDE5) inhibitor
avena barbata pollen	non-standardized pollen allergenic extract
avena fatua pollen	non-standardized pollen allergenic extract
avena sativa pollen	non-standardized pollen allergenic extract

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avibactam	beta lactamase inhibitor
avocado	non-standardized food allergenic extract
axitinib	kinase inhibitor
azacitidine	nucleoside metabolic inhibitor
azathioprine	purine antimetabolite
azelastine	histamine-1 receptor antagonist
azficel-t	autologous cultured cell
azilsartan	angiotensin II receptor blocker
azithromycin	macrolide antimicrobial
azithromycin anhydrous	macrolide antimicrobial
aztreonam	monobactam antibacterial
baccharis halimifolia pollen	non-standardized pollen allergenic extract
baccharis salicina pollen	non-standardized pollen allergenic extract
bacillus anthracis strain v770-np1-r antigen	live attenuated Bacillus anthracis vaccine
bacillus calmette-guerin substrain tice live antigen	live attenuated Bacillus Calmette-Guerin immunotherapy
bacillus calmette-guerin substrain tice live antigen	live attenuated Bacillus Calmette-Guerin vaccine
backusella lamprospora	non-standardized fungal allergenic extract
baclofen	GABA A agonist
balsalazide	aminosalicylate
balsam peru	standardized chemical allergen
balsamorhiza sagittata pollen	non-standardized pollen allergenic extract
banana	non-standardized food allergenic extract
barley	non-standardized food allergenic extract

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barley malt	non-standardized food allergenic extract
barley malt	non-standardized plant allergenic extract
basil	non-standardized food allergenic extract
basil	non-standardized plant allergenic extract
basiliximab	interleukin-2 receptor blocking antibody
bassia hyssopifolia pollen	non-standardized pollen allergenic extract
bassia scoparia pollen	non-standardized pollen allergenic extract
bay leaf	non-standardized food allergenic extract
bay leaf	non-standardized plant allergenic extract
bazedoxifene	estrogen agonist/antagonist
bean	non-standardized food allergenic extract
becaplermin	human platelet-derived growth factor
beckmannia eruciformis pollen	non-standardized pollen allergenic extract
beclomethasone	corticosteroid
bedaquiline	diarylquinoline antimycobacterial
beef	non-standardized food allergenic extract
beef liver	non-standardized food allergenic extract
beet	non-standardized food allergenic extract
beet	non-standardized plant allergenic extract
belatacept	selective T-cell costimulation blocker
belimumab	B-Lymphocyte stimulator (BLyS)-specific inhibitor
belinostat	histone deacetylase (HDAC) inhibitor
benazepril	angiotensin converting enzyme inhibitor
benazeprilat	angiotensin converting enzyme inhibitor
bendamustine	alkylating drug
bendroflumethiazide	thiazide diuretic

	EDA Establishad Dhammasalania Olasa (EDO) Taut Dhasa
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benzocaine	standardized chemical allergen
benzoic acid	nitrogen binding agent
benzonatate	non-narcotic antitussive
benzphetamine	sympathomimetic amine anorectic
benztropine	anticholinergic
benztropine	antihistamine
benzyl alcohol	pediculicide
benzylparaben	standardized chemical allergen
bepotastine	histamine-1 (H1) receptor antagonist
beractant	surfactant
besifloxacin	quinolone antimicrobial
beta vulgaris pollen	non-standardized pollen allergenic extract
betaine	methylating agent
betamethasone	corticosteroid
betaxolol	beta adrenergic blocker
bethanechol	muscarinic agonist
betula alleghaniensis pollen	non-standardized pollen allergenic extract
betula lenta pollen	non-standardized pollen allergenic extract
betula nigra pollen	non-standardized pollen allergenic extract
betula occidentalis pollen	non-standardized pollen allergenic extract
betula papyrifera pollen	non-standardized pollen allergenic extract
betula pendula pollen	non-standardized pollen allergenic extract
betula populifolia pollen	non-standardized pollen allergenic extract
bevacizumab	vascular endothelial growth factor (VEGF) directed antibody
bexarotene	retinoid
bicalutamide	androgen receptor inhibitor

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bimatoprost	prostaglandin analog
biperiden	anticholinergic
bisacodyl	stimulant laxative
bismuth cation	bismuth
bismuth subsalicylate	bismuth
bisoprolol	beta adrenergic blocker
bisphenol a diglycidyl ether	standardized chemical allergen
bivalirudin	anti-coagulant anti-coagulant
bivalirudin	direct thrombin inhibitor
black olive	non-standardized food allergenic extract
black pepper	non-standardized food allergenic extract
black raspberry	non-standardized food allergenic extract
black sea bass	non-standardized food allergenic extract
black walnut	non-standardized food allergenic extract
black-eyed pea	non-standardized food allergenic extract
blatella germanica	non-standardized insect allergenic extract
blatta orientalis	non-standardized insect allergenic extract
bleomycin	cytoprotective agent
blue crab	non-standardized food allergenic extract
bluefish	non-standardized food allergenic extract
boceprevir	hepatitis C virus (HCV) NS3/4A protease inhibitor
bombyx mori fiber	non-standardized insect allergenic extract
bordetella pertussis filamentous	
hemagglutinin antigen (formaldehyde	inactivated Bordetella pertussis vaccine
inactivated)	
bordetella pertussis fimbriae 2/3 antigen	inactivated Bordetella pertussis vaccine

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bordetella pertussis pertactin antigen (formaldehyde inactivated)	inactivated Bordetella pertussis vaccine
bordetella pertussis toxoid antigen (formaldehyde, glutaraldehyde inactivated)	inactivated Bordetella pertussis vaccine
bordetella pertussis toxoid antigen (glutaraldehyde inactivated)	inactivated Bordetella pertussis vaccine
bortezomib	proteasome inhibitor
bos taurus dander	non-standardized animal dander allergenic extract
bos taurus hair	non-standardized animal hair allergenic extract
bos taurus skin	non-standardized animal skin allergenic extract
bosentan	endothelin receptor antagonist
bosentan anhydrous	endothelin receptor antagonist
bosutinib	kinase inhibitor
botrytis cinerea	non-standardized fungal allergenic extract
botulinum toxin type a	acetylcholine release inhibitor
bouteloua gracilis pollen	non-standardized pollen allergenic extract
bovine type i collagen	allogeneic cultured cell scaffold
boysenberry	non-standardized food allergenic extract
boysenberry	non-standardized plant allergenic extract
brassica nigra pollen	non-standardized pollen allergenic extract
brassica rapa pollen	non-standardized pollen allergenic extract
brazil nut	non-standardized food allergenic extract
brentuximab vedotin	CD30-directed antibody-drug conjugate
brimonidine	alpha adrenergic agonist
brinzolamide	carbonic anhydrase inhibitor

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase
	PLR regulations require that the following statement is included in the Highlights
	Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
Active Molety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
	For more information about how FDA determines the EPC Text Phrase, see the 2009
	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
briza media pollen	non-standardized pollen allergenic extract
broccoli	non-standardized food allergenic extract
bromfenac	nonsteroidal anti-inflammatory drug
bromocriptine	ergot derivative
bromus carinatus pollen	non-standardized pollen allergenic extract
bromus catharticus pollen	non-standardized pollen allergenic extract
bromus ciliatus pollen	non-standardized pollen allergenic extract
bromus grandis pollen	non-standardized pollen allergenic extract
bromus hordeaceus pollen	non-standardized pollen allergenic extract
bromus inermis pollen	non-standardized pollen allergenic extract
bromus marginatus pollen	non-standardized pollen allergenic extract
bromus rubens pollen	non-standardized pollen allergenic extract
bromus secalinus pollen	non-standardized pollen allergenic extract
bronopol	standardized chemical allergen
brook trout	non-standardized food allergenic extract
broussonetia papyrifera pollen	non-standardized pollen allergenic extract
brussels sprout	non-standardized food allergenic extract
brussels sprout	non-standardized plant allergenic extract
buckwheat	non-standardized food allergenic extract
budesonide	corticosteroid
bullhead, unspecified	non-standardized food allergenic extract
bumetanide	loop diuretic
bupivacaine	amide local anesthetic
buprenorphine	partial opioid agonist
bupropion	aminoketone
busulfan	alkylating drug

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
butalbital	barbiturate
butenafine	benzylamine antifungal
butoconazole	azole antifungal
butorphanol	opioid agonist/antagonist
butternut squash	non-standardized food allergenic extract
butylparaben	standardized chemical allergen
cabazitaxel	microtubule inhibitor
cabbage	non-standardized food allergenic extract
cabergoline	ergot derivative
cabozantinib	kinase inhibitor
caffeine	central nervous system stimulant
caffeine	methylxanthine
calcipotriene	vitamin D analog
calcitonin salmon	calcitonin
calcitriol	vitamin D3 analog
calcium	calcium
calcium	phosphate binder
calcium cation	blood coagulation factor
calfactant	surfactant
california blackberry	non-standardized food allergenic extract
california blackberry	non-standardized plant allergenic extract
callistemon citrinus pollen	non-standardized pollen allergenic extract
calocedrus decurrens pollen	non-standardized pollen allergenic extract
camelus bactrianus hair	non-standardized animal hair allergenic extract
camponotus pennsylvanicus	non-standardized insect venom allergenic extract
canagliflozin anhydrous	sodium-glucose co-transporter 2 (SGLT2) inhibitor

	EDA Establisha d Dhamasa alawis Olasa (EDO) Tarri Dhamasa
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
candesartan	angiotensin II receptor blocker
candida albicans	non-standardized fungal allergenic extract
candida tropicalis	non-standardized fungal allergenic extract
canis lupus familiaris dander	non-standardized animal dander allergenic extract
canis lupus familiaris hair	non-standardized animal hair allergenic extract
canis lupus familiaris skin	non-standardized animal skin allergenic extract
cannabis sativa pollen	non-standardized pollen allergenic extract
cantaloupe	non-standardized food allergenic extract
capecitabine	nucleoside metabolic inhibitor
capra hircus dander	non-standardized animal dander allergenic extract
capra hircus hair	non-standardized animal hair allergenic extract
capra hircus skin	non-standardized animal skin allergenic extract
capreomycin	antimycobacterial
capsicum	non-standardized food allergenic extract
capsicum	non-standardized plant allergenic extract
captopril	angiotensin converting enzyme inhibitor
caraway seed	non-standardized food allergenic extract
caraway seed	non-standardized plant allergenic extract
carbachol	cholinergic agonist
carbamazepine	antiepileptic drug (AED)
carbamazepine	mood stabilizer
carbamoylcholine	cholinergic agonist
carbenicillin	penicillin class antibacterial
carbidopa	aromatic amino acid decarboxylation inhibitor
carbinoxamine	histamine-1 (H1) receptor antagonist
carbon dioxide	radiographic contrast agent

	EDA Establisha d Dhamasa alawia Olasa (EDO) Tarri Dhamasa
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
carboplatin	platinum-based drug
carboprost	prostaglandin analog
carex barbarae pollen	non-standardized pollen allergenic extract
carfilzomib	proteasome inhibitor
carglumic acid	Carbamoyl Phosphate Synthetase 1 (CPS 1) activator
carisoprodol	muscle relaxant
carmustine	alkylating drug
carob	non-standardized food allergenic extract
carob	non-standardized plant allergenic extract
carpinus betulus pollen	non-standardized pollen allergenic extract
carpinus caroliniana pollen	non-standardized pollen allergenic extract
carrot	non-standardized food allergenic extract
carteolol	beta adrenergic blocker
carvedilol	alpha adrenergic blocker
carvedilol	beta adrenergic blocker
carya alba pollen	non-standardized pollen allergenic extract
carya cordiformis pollen	non-standardized pollen allergenic extract
carya glabra pollen	non-standardized pollen allergenic extract
carya illinoinensis pollen	non-standardized pollen allergenic extract
carya laciniosa pollen	non-standardized pollen allergenic extract
carya ovata pollen	non-standardized pollen allergenic extract
casein	non-standardized food allergenic extract
cashew	non-standardized food allergenic extract
caspofungin	echinocandin antifungal
cassava	non-standardized food allergenic extract
cassava	non-standardized plant allergenic extract

	FDA Fetablished Dharmacalagis Class (FDC) Toyt Dhrees
	FDA Established Pharmacologic Class (EPC) Text Phrase
	PLR regulations require that the following statement is included in the Highlights
	Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
Active Meiety Neme	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
Active Moiety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
	For more information about how FDA determines the EPC Text Phrase, see the 2009
	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
castanea dentata pollen	non-standardized pollen allergenic extract
casuarina equisetifolia pollen	non-standardized pollen allergenic extract
casuarina glauca pollen	non-standardized pollen allergenic extract
cauliflower	non-standardized food allergenic extract
cauliflower	non-standardized plant allergenic extract
cavia porcellus dander	non-standardized animal dander allergenic extract
cavia porcellus hair	non-standardized animal hair allergenic extract
cavia porcellus skin	non-standardized animal skin allergenic extract
cedrus atlantica pollen	non-standardized pollen allergenic extract
cedrus deodara pollen	non-standardized pollen allergenic extract
cefaclor	cephalosporin antibacterial
cefaclor anhydrous	cephalosporin antibacterial
cefadroxil	cephalosporin antibacterial
cefadroxil anhydrous	cephalosporin antibacterial
cefazolin	cephalosporin antibacterial
cefdinir	cephalosporin antibacterial
cefditoren	cephalosporin antibacterial
cefepime	cephalosporin antibacterial
cefixime	cephalosporin antibacterial
cefixime anhydrous	cephalosporin antibacterial
cefoperazone	cephalosporin antibacterial
cefotaxime	cephalosporin antibacterial
cefotetan	cephalosporin antibacterial
cefoxitin	cephalosporin antibacterial
cefpodoxime	cephalosporin antibacterial
cefprozil	cephalosporin antibacterial

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights  Indications and Usage heading if a drug is a member of an EPC [see 21 CFR  201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each  listed active moiety, the associated FDA EPC text phrase is included in this document.  For more information about how FDA determines the EPC Text Phrase, see the 2009  "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for  Use in the Highlights" MAPP 7400.13.
ceftaroline	cephalosporin antibacterial
ceftazidime	cephalosporin antibacterial
ceftazidime anhydrous	cephalosporin antibacterial
ceftibuten	cephalosporin antibacterial
ceftizoxime	cephalosporin antibacterial
ceftriaxone	cephalosporin antibacterial
cefuroxime	cephalosporin antibacterial
ceiba pentandra fiber	non-standardized plant fiber allergenic extract
celecoxib	nonsteroidal anti-inflammatory drug
celery	non-standardized food allergenic extract
cellulose sodium phosphate	calcium binder
celtis laevigata pollen	non-standardized pollen allergenic extract
celtis occidentalis pollen	non-standardized pollen allergenic extract
centaurea stoebe pollen	non-standardized pollen allergenic extract
centruroides fab2 antivenin (equine)	antivenin
cephalexin	cephalosporin antibacterial
cephalexin anhydrous	cephalosporin antibacterial
cephalosporium roseum	non-standardized fungal allergenic extract
cephradine	cephalosporin antibacterial
cephradine anhydrous	cephalosporin antibacterial
ceritinib	kinase inhibitor
certolizumab	tumor necrosis factor (TNF) blocker
certolizumab pegol	tumor necrosis factor (TNF) blocker
cetirizine	histamine-1 (H1) receptor antagonist
cetrorelix	gonadotropin releasing hormone (GnRH) antagonist
cetuximab	epidermal growth factor receptor (EGFR) antagonist

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
cevimeline	cholinergic agonist
chaetomium globosum	non-standardized fungal allergenic extract
chaetomium indicum	non-standardized fungal allergenic extract
chamaecyparis lawsoniana pollen	non-standardized pollen allergenic extract
chamaecyparis thyoides pollen	non-standardized pollen allergenic extract
chamaerops humilis pollen	non-standardized pollen allergenic extract
chenopodium album pollen	non-standardized pollen allergenic extract
chenopodium ambrosioides pollen	non-standardized pollen allergenic extract
chenopodium murale pollen	non-standardized pollen allergenic extract
cherry	non-standardized food allergenic extract
chicken	non-standardized food allergenic extract
chickpea	non-standardized food allergenic extract
chickpea	non-standardized plant allergenic extract
chive	non-standardized food allergenic extract
chive	non-standardized plant allergenic extract
chlorambucil	alkylating drug
chloramphenicol	amphenicol class antibacterial
chlordiazepoxide	benzodiazepine
chloris barbata pollen	non-standardized pollen allergenic extract
chloris gayana pollen	non-standardized pollen allergenic extract
chloris verticillata pollen	non-standardized pollen allergenic extract
chloris virgata pollen	non-standardized pollen allergenic extract
chloroprocaine	ester local anesthetic
chloroquine	antimalarial
chlorothiazide	thiazide diuretic

	EDA Established Dharmanalagia Class (EDC) Tayt Dhrees
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
chlorpheniramine	histamine-1 (H1) receptor antagonist
chlorpromazine	phenothiazine
chlorpropamide	sulfonylurea
chlorquinaldol	standardized chemical allergen
chlorthalidone	thiazide-like diuretic
chlorzoxazone	muscle relaxant
cholecalciferol	vitamin D
cholestyramine	bile acid sequestrant
cholic acid	bile acid
choriogonadotropin alfa	gonadotropin
chromate ion cr-51	radioactive diagnostic agent
chromated cr-51 serum albumin	radioactive diagnostic agent
chromic phosphate p-32	radioactive therapeutic agent
chromium	standardized chemical allergen
chrysonilia sitophila	non-standardized fungal allergenic extract
cidofovir	nucleoside analog CMV DNA polymerase inhibitor
cidofovir anhydrous	nucleoside analog CMV DNA polymerase inhibitor
cilastatin	renal dehydropeptidase inhibitor
cilostazol	phosphodiesterase-3 inhibitor
cimetidine	histamine-2 (H2) receptor antagonist
cinacalcet	calcium-sensing receptor agonist
cinnamaldehyde	standardized chemical allergen
cinnamon	non-standardized food allergenic extract
cinnamyl alcohol	standardized chemical allergen
ciprofloxacin	quinolone antimicrobial
cisatracurium	nondepolarizing neuromuscular blocker

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document.  For more information about how FDA determines the EPC Text Phrase, see the 2009  "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
cisplatin	platinum-based drug
citalopram	selective serotonin reuptake inhibitor (SSRI)
citrus sinensis pollen	non-standardized pollen allergenic extract
cladosporium cladosporioides	non-standardized fungal allergenic extract
cladosporium herbarum	non-standardized fungal allergenic extract
cladosporium sphaerospermum	non-standardized fungal allergenic extract
cladribine	purine antimetabolite
clarithromycin	macrolide antimicrobial
clavulanic acid	beta lactamase inhibitor
clevidipine	dihydropyridine calcium channel blocker
clidinium	anticholinergic
clindamycin	lincosamide antibacterial
clioquinol	standardized chemical allergen
clobazam	benzodiazepine
clobetasol	corticosteroid
clocortolone	corticosteroid
clofarabine	nucleoside metabolic inhibitor
clofazimine	antimycobacterial
clomiphene	estrogen agonist/antagonist
clomipramine	tricyclic antidepressant (TCA)
clonazepam	benzodiazepine
clonidine	central alpha-2 adrenergic agonist
clonostachys rosea f. rosea	non-standardized fungal allergenic extract
clopidogrel	P2Y12 platelet inhibitor
clorazepic acid	benzodiazepine

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights  Indications and Usage heading if a drug is a member of an EPC [see 21 CFR  201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document.  For more information about how FDA determines the EPC Text Phrase, see the 2009  "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
clostridium tetani toxoid antigen (formaldehyde inactivated)	inactivated Clostridium tetani vaccine
clotrimazole	azole antifungal
clove	non-standardized food allergenic extract
clove	non-standardized plant allergenic extract
clozapine	atypical antipsychotic
coagulation factor ix human	human blood coagulation factor
coagulation factor ix recombinant human	human blood coagulation factor
coagulation factor vii human	human blood coagulation factor
coagulation factor viia human	human blood coagulation factor
coagulation factor viia recombinant human	human blood coagulation factor
coagulation factor x human	human blood coagulation factor
cobalt	standardized chemical allergen
cobicistat	CYP3A inhibitor
coccidioides immitis spherule	skin test antigen
cochliobolus heterostrophus	non-standardized fungal allergenic extract
cochliobolus lunatus	non-standardized fungal allergenic extract
cochliobolus sativus	non-standardized fungal allergenic extract
cochliobolus spicifer	non-standardized fungal allergenic extract
cocoa	non-standardized food allergenic extract
coconut	non-standardized food allergenic extract
cod, unspecified	non-standardized food allergenic extract
codeine	opioid agonist
codeine anhydrous	opioid agonist
coffee bean	non-standardized food allergenic extract

	EDA Establishad Dhamasada via Olasa (EDA) Taut Dhamas
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
cola acuminata seed	non-standardized food allergenic extract
cola acuminata seed	non-standardized plant allergenic extract
colesevelam	bile acid sequestrant
colestipol	bile acid sequestrant
colistimethate	polymixin class antibacterial
collagenase	collagen-specific enzyme
colletotrichum coccodes	non-standardized fungal allergenic extract
common carp	non-standardized food allergenic extract
concord grape	non-standardized food allergenic extract
concord grape	non-standardized plant allergenic extract
conivaptan	vasopressin antagonist
copper	copper-containing intrauterine device (IUD)
corcorus capsularis fiber	non-standardized plant fiber allergenic extract
corn	non-standardized food allergenic extract
corn grain	non-standardized food allergenic extract
corn grain	non-standardized plant allergenic extract
cornus florida pollen	non-standardized pollen allergenic extract
cornus nuttallii pollen	non-standardized pollen allergenic extract
cortaderia selloana pollen	non-standardized pollen allergenic extract
corticotropin	adrenocorticotropic hormone
cortisone	corticosteroid
corylus americana pollen	non-standardized pollen allergenic extract
corylus avellana pollen	non-standardized pollen allergenic extract
corylus cornuta subsp. californica pollen	non-standardized pollen allergenic extract
corynebacterium diphtheriae toxoid antigen (formaldehyde inactivated)	inactivated Corynebacterium diphtheriae vaccine

	EDA Establishad Dhamasadania Olasa (EDO) Taut Dhasa
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
cosmos bipinnatus pollen	non-standardized pollen allergenic extract
cosyntropin	adrenocorticotropic hormone
cotton fiber	non-standardized plant fiber allergenic extract
cotton seed cottonmouth (agkistrodon piscivorus) immune	non-standardized plant allergenic extract
fab antivenin (ovine)	antivenin
cow milk	non-standardized food allergenic extract
crab leg, unspecified	non-standardized food allergenic extract
cranberry	non-standardized food allergenic extract
cranberry	non-standardized plant allergenic extract
crataegus monogyna pollen	non-standardized pollen allergenic extract
crizotinib	kinase inhibitor
crofelemer	antidiarrheal
cromolyn	mast cell stabilizer
cryptomeria japonica pollen	non-standardized pollen allergenic extract
ctenocephalides canis	non-standardized insect allergenic extract
ctenocephalides felis	non-standardized insect allergenic extract
cucumber	non-standardized food allergenic extract
cultivated mushroom	non-standardized food allergenic extract
cumin	non-standardized food allergenic extract
cumin	non-standardized plant allergenic extract
cupressus arizonica pollen	non-standardized pollen allergenic extract
cupressus macrocarpa pollen	non-standardized pollen allergenic extract
cupressus sempervirens pollen	non-standardized pollen allergenic extract
curcuma angustifolia root	non-standardized food allergenic extract
curcuma angustifolia root	non-standardized plant allergenic extract

	FDA Fotoblished Dheymandleric Class (FDC) Toy/ Dhyses
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
curvularia inaequalis	non-standardized fungal allergenic extract
cyanocobalamin	vitamin B12
cyanocobalamin co-57	radioactive diagnostic agent
cyclachaena xanthifolia pollen	non-standardized pollen allergenic extract
cyclobenzaprine	muscle relaxant
cyclophosphamide	alkylating drug
cyclophosphamide anhydrous	alkylating drug
cyclosporine	calcineurin inhibitor immunosuppressant
cynodon dactylon pollen	standardized pollen allergenic extract
cynosurus cristatus pollen	non-standardized pollen allergenic extract
cysteamine	cystine depleting agent
cytarabine	nucleoside metabolic inhibitor
cytisus scoparius flowering top	non-standardized plant allergenic extract
cytisus scoparius pollen	non-standardized pollen allergenic extract
dabrafenib	kinase inhibitor
dacarbazine	alkylating drug
daclizumab	interleukin-2 receptor blocking antibody
dactinomycin	actinomycin
dactylis glomerata pollen	standardized pollen allergenic extract
dalfopristin	streptogramin antibacterial
dalteparin	anti-coagulant anti-coagulant
dalteparin	low molecular weight heparin (LMWH)
danazol	androgen
dantrolene	skeletal muscle relaxant
dapagliflozin	sodium-glucose co-transporter 2 (SGLT2) inhibitor
dapiprazole	alpha adrenergic blocker

	FDA Fa(al-l'al-al-Dhamasaalan'a Olasa (FDO) Tant Dhamasa
	FDA Established Pharmacologic Class (EPC) Text Phrase
	PLR regulations require that the following statement is included in the Highlights
	Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
Active Moiety Name	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
Active Molety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
	For more information about how FDA determines the EPC Text Phrase, see the 2009
	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
dapsone	sulfone
daptomycin	lipopeptide antibacterial
darbepoetin alfa	erythropoiesis-stimulating agent (ESA)
darifenacin	muscarinic antagonist
darunavir	HIV protease inhibitor
dasatinib	kinase inhibitor
dasatinib anhydrous	kinase inhibitor
date	non-standardized food allergenic extract
date	non-standardized plant allergenic extract
daucus carota subsp. carota pollen	non-standardized pollen allergenic extract
daunorubicin	anthracycline topoisomerase inhibitor
decitabine	nucleoside metabolic inhibitor
deferasirox	iron chelator
deferiprone	iron chelator
deferoxamine	iron chelator
delavirdine	HIV nonnucleoside analog reverse transcriptase inhibitor (HIV-1 NNRTI)
demeclocycline	tetracycline class antimicrobial
dendryphiella vinosa	non-standardized fungal allergenic extract
denileukin diftitox	CD25-directed cytotoxin
denosumab	RANK ligand (RANKL) inhibitor
dermatophagoides farinae	standardized insect protein allergenic extract
dermatophagoides pteronyssinus	standardized insect protein allergenic extract
deserpidine	catecholamine-depleting sympatholytic
desflurane	general anesthetic
desipramine	tricyclic antidepressant (TCA)
desirudin	anti-coagulant

	EDA Fotoklick od Dkommonologie Ologe (EDO) Toyt Dkygge
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
desirudin	direct thrombin inhibitor
desloratadine	histamine-1 (H1) receptor antagonist
desmopressin	factor VIII activator
desmopressin	vasopressin analog
desogestrel	progestin
desonide	corticosteroid
desoximetasone	corticosteroid
desvenlafaxine	serotonin and norepinephrine reuptake inhibitor (SNRI)
dexamethasone	corticosteroid
dexlansoprazole	proton pump inhibitor
dexmedetomidine	central alpha-2 adrenergic agonist
dexmethylphenidate	central nervous system stimulant
dexrazoxane	cytoprotective agent
dextran 40	plasma volume expander
dextran 70	plasma volume expander
dextran 75	plasma volume expander
dextroamphetamine	central nervous system stimulant
dextromethorphan	sigma-1 agonist
dextromethorphan	uncompetitive NMDA receptor antagonist
diatrizoic acid	radiographic contrast agent
diazepam	benzodiazepine
diazolidinyl urea	standardized chemical allergen
dibucaine	standardized chemical allergen
diclofenac	nonsteroidal anti-inflammatory drug
dicloxacillin	penicillin class antibacterial
dicoria canescens pollen	non-standardized pollen allergenic extract

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dicyclomine	anticholinergic
didanosine	HIV nucleoside analog reverse transcriptase inhibitors (HIV NRTI)
dienogest	progestin
diethylcarbamazine	anthelmintic
diethylpropion	sympathomimetic amine anorectic
difenoxin	antidiarrheal
diflorasone	corticosteroid
diflunisal	nonsteroidal anti-inflammatory drug
digoxin	cardiac glycoside
dihydrocodeine	opioid agonist
dihydroergotamine	ergotamine derivative
dill	non-standardized food allergenic extract
dill	non-standardized plant allergenic extract
diltiazem	nondihydropyridine calcium channel blocker
dimercaprol	metal chelator
dinoprostone	prostaglandin analog
dipentamethylenethiuram disulfide	standardized chemical allergen
diphenhydramine	histamine-1 (H1) receptor antagonist
diphenidol	antiemetic
diphenoxylate	antidiarrheal
diphenylguanidine	standardized chemical allergen
dipivefrin	adrenergic agonist
dipyridamole	platelet aggregation inhibitor
disopyramide	antiarrhythmic
disperse blue 106	standardized chemical allergen
distichlis spicata pollen	non-standardized pollen allergenic extract

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distinhlia aniasta suban atriata nallan	Use in the Highlights" MAPP 7400.13.  non-standardized pollen allergenic extract
distichlis spicata subsp. stricta pollen disulfiram	i v
ditiocarb zinc	aldehyde dehydrogenase inhibitor
	standardized chemical allergen
dobutamine	beta adrenergic agonist
docetaxel	microtubule inhibitor
docetaxel anhydrous	microtubule inhibitor
dofetilide	antiarrhythmic
dolasetron	serotonin-3 (5-HT3) receptor antagonist
dolichovespula arenaria venom protein	standardized insect venom protein allergenic extract
dolichovespula maculata venom protein	standardized insect venom protein allergenic extract
dolutegravir	human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI)
donepezil	cholinesterase inhibitor
dopamine	catecholamine
doripenem	penem antibacterial
dornase alfa	recombinant human deoxyribonuclease 1 (rhDNase) enzyme
dorzolamide	carbonic anhydrase inhibitor
doxapram	respiratory stimulant
doxazosin	alpha adrenergic blocker
doxepin	tricyclic antidepressant (TCA)
doxercalciferol	vitamin D2 analog
doxorubicin	anthracycline topoisomerase inhibitor
doxycycline	tetracycline class drug
dronabinol	cannabinoid
dronedarone	antiarrhythmic
droperidol	dopamine-2 (D2) antagonist
drospirenone	progestin

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	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
drotrecogin alfa (activated)	recombinant activated protein C
duck	non-standardized food allergenic extract
duloxetine	serotonin and norepinephrine reuptake inhibitor (SNRI)
dutasteride	5-alpha reductase inhibitor
dysphania botrys pollen	non-standardized pollen allergenic extract
	non standardized policin dilengenie extract
eastern diamondback rattlesnake (crotalus	antivenin
adamanteus) immune fab antivenin (ovine)	
echinochloa crus-galli pollen	non-standardized pollen allergenic extract
echothiophate	cholinesterase inhibitor
econazole	azole antifungal
eculizumab	complement inhibitor
edetic acid	anti-coagulant anti-coagulant
edetic acid	lead chelator
edoxaban	factor Xa inhibitor
edrophonium	cholinesterase inhibitor
efalizumab	CD11a-directed humanized IgG1 antibody
efavirenz	HIV nonnucleoside analog reverse transcriptase inhibitor (HIV-1 NNRTI)
efinaconazole	azole antifungal
eflornithine	antiprotozoal
eflornithine	decarboxylase inhibitor
egg	non-standardized food allergenic extract
egg white	non-standardized food allergenic extract
egg yolk	non-standardized food allergenic extract
eggplant	non-standardized food allergenic extract
eggplant	non-standardized plant allergenic extract

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elaeagnus angustifolia pollen	non-standardized pollen allergenic extract
eletriptan	serotonin 5-HT1B/1D receptor agonist (triptan)
eliglustat	glucosylceramide synthase inhibitor
elosulfase alfa	hydrolytic lysozomal glycosaminoglycan (GAG)-specific enzyme
eltrombopag	thrombopoiesis stimulating agent
elvitegravir	HIV integrase strand transfer inhibitor (HIV-1 INSTI)
elymus glaucus pollen	non-standardized pollen allergenic extract
elymus repens pollen	non-standardized pollen allergenic extract
elymus trachycaulus pollen	non-standardized pollen allergenic extract
emedastine	histamine-1 (H1) inhibitor
empagliflozin	sodium-glucose co-transporter 2 (SGLT2) inhibitor
emtricitabine	HIV nucleoside analog reverse transcriptase inhibitors (HIV NRTI)
enalapril	angiotensin converting enzyme inhibitor
enalaprilat anhydrous	angiotensin converting enzyme inhibitor
encelia farinosa pollen	non-standardized pollen allergenic extract
enflurane	general anesthetic
enfuvirtide	HIV fusion inhibitor (HIV-1 FI)
english sole	non-standardized food allergenic extract
english walnut	non-standardized food allergenic extract
enoxaparin	low molecular weight heparin (LMWH)
entacapone	catechol o-methyl transferase (COMT) inhibitor
entecavir	HBV nucleoside analog reverse transcriptase inhibitor (HBV-NRTI)
entecavir anhydrous	HBV nucleoside analog reverse transcriptase inhibitor (HBV-NRTI)
enzalutamide	androgen receptor inhibitor
ephedra californica pollen	non-standardized pollen allergenic extract
epicoccum nigrum	non-standardized fungal allergenic extract

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A ativa Maiatu Nama	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
Active Moiety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
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	Use in the Highlights" MAPP 7400.13.
epidermophyton floccosum	non-standardized fungal allergenic extract
epidermophyton inguinale	non-standardized fungal allergenic extract
epilobium angustifolium pollen	non-standardized pollen allergenic extract
epinostine	adrenergic agonist
epinastine	histamine-1 (H1) inhibitor
epinephrine	alpha adrenergic agonist
epinephrine	beta adrenergic agonist
	catecholamine
epinephrine epirubicin	anthracycline topoisomerase inhibitor
epirabicin	aldosterone antagonist
epoprostenol	prostacycline vasodilator
	angiotensin II receptor blocker
eprosartan	<u> </u>
eptifibatide equine botulinum neurotoxin a/b immune	platelet aggregation inhibitor
globulin	immunoglobulin G
equine thymocyte immune globulin	immunoglobulin G
equus caballus dander	non-standardized animal dander allergenic extract
equus caballus hair	horse
equus caballus hair	non-standardized animal hair allergenic extract
equus caballus skin	non-standardized animal skin allergenic extract
eragrostis cilianensis pollen	non-standardized pollen allergenic extract
eragrostis variabilis pollen	non-standardized pollen allergenic extract
ergocalciferol	provitamin D2 compound
ergoloids	ergotamine derivative
ergotamine	ergotamine derivative
eribulin	microtubule inhibitor

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Active Molety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
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ericameria nauseosa pollen	non-standardized pollen allergenic extract
erlotinib	kinase inhibitor
ertapenem	penem antibacterial
erysimum cheiri pollen	non-standardized pollen allergenic extract
erythromycin	macrolide
erythromycin	macrolide antimicrobial
erythropoietin	erythropoiesis-stimulating agent (ESA)
escarole	non-standardized food allergenic extract
escarole	non-standardized plant allergenic extract
escitalopram	selective serotonin reuptake inhibitor (SSRI)
esmolol	beta adrenergic blocker
esomeprazole	proton pump inhibitor
estazolam	benzodiazepine
estradiol	estrogen
estramustine	alkylating drug
estrogens, conjugated	estrogen
etanercept	tumor necrosis factor (TNF) blocker
ethacrynic acid	loop diuretic
ethambutol	antimycobacterial
ethinyl estradiol	estrogen
ethiodized oil	radiographic contrast agent
ethionamide	antimycobacterial
ethosuximide	antiepileptic drug (AED)
ethotoin	antiepileptic drug (AED)
ethylenediamine	standardized chemical allergen
ethylparaben	standardized chemical allergen

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
ethynodiol	progestin
etidronic acid	bisphosphonate
etodolac	nonsteroidal anti-inflammatory drug
etomidate	general anesthetic
etonogestrel	progestin
etoposide	topoisomerase inhibitor
etravirine	HIV nonnucleoside analog reverse transcriptase inhibitor (HIV-1 NNRTI)
eucalyptus globulus pollen	non-standardized pollen allergenic extract
eugenol	standardized chemical allergen
eupatorium capillifolium pollen	non-standardized pollen allergenic extract
european gooseberry	non-standardized food allergenic extract
european gooseberry	non-standardized plant allergenic extract
european pilchard	non-standardized food allergenic extract
eurotium amstelodami	non-standardized fungal allergenic extract
eurotium herbariorum	non-standardized fungal allergenic extract
evernia prunastri	standardized chemical allergen
everolimus	kinase inhibitor
exemestane	aromatase inhibitor
exenatide	GLP-1 receptor agonist
ezetimibe	dietary cholesterol absorption inhibitor
ezogabine	potassium channel opener
factor xiii concentrate (human)	human blood coagulation factor
fagus grandifolia pollen	non-standardized pollen allergenic extract
fagus sylvatica pollen	non-standardized pollen allergenic extract
famciclovir	nucleoside analog HSV DNA polymerase inhibitor / VZV DNA polymerase inhibitor

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	Use in the Highlights" MAPP 7400.13.
famotidine	histamine-2 (H2) receptor antagonist
febuxostat	xanthine oxidase inhibitor
felbamate	antiepileptic drug (AED)
felis catus hair	standardized animal hair allergenic extract
felis catus skin	standardized animal nali dilergenic extract
felodipine	dihydropyridine calcium channel blocker
fenofibrate	peroxisome proliferator-activated receptor (PPAR) alpha agonist
fenofibric acid	peroxisome proliferator-activated receptor (PPAR) alpha agonist
fenoldopam	dopaminergic agonist
fenoprofen	nonsteroidal anti-inflammatory drug
fentanyl	opioid agonist
ferric cation	iron replacement product
ferric cation	phosphate binder
ferric oxyhydroxide	phosphate binder
ferumoxides non-stoichiometric magnetite	paramagnetic contrast agent
ferumoxytol non-stoichiometric magnetite	iron replacement product
festuca ovina pollen	non-standardized pollen allergenic extract
festuca pratensis pollen	standardized pollen allergenic extract
festuca rubra pollen	non-standardized pollen allergenic extract
fexofenadine	histamine-1 (H1) receptor antagonist
fibrinogen human	human blood coagulation factor
fidaxomicin	macrolide antibacterial
fig	non-standardized food allergenic extract
fig	non-standardized plant allergenic extract
filgrastim	leukocyte growth factor

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finasteride	5-alpha reductase inhibitor
fingolimod	sphingosine 1-phosphate receptor modulator
flavoxate	muscarinic antagonist
flax seed	non-standardized food allergenic extract
flax seed	non-standardized plant allergenic extract
flecainide	antiarrhythmic
florbetaben f-18	radioactive diagnostic agent
florbetapir f-18	radioactive diagnostic agent
flounder	non-standardized food allergenic extract
floxuridine	antimetabolite
fluconazole	azole antifungal
flucytosine	nucleoside analog antifungal
fludarabine	nucleoside metabolic inhibitor
fludeoxyglucose f-18	radioactive diagnostic agent
flumazenil	benzodiazepine antagonist
flunisolide	corticosteroid
flunisolide anhydrous	corticosteroid
fluocinolone acetonide	corticosteroid
fluocinonide	corticosteroid
fluorescein	diagnostic dye
fluoride ion f-18	radioactive diagnostic agent
fluorometholone	corticosteroid
fluorouracil	nucleoside metabolic inhibitor
fluoxetine	selective serotonin reuptake inhibitor (SSRI)
fluoxymesterone	androgen
fluphenazine	phenothiazine

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flurandrenolide	corticosteroid
flurazepam	benzodiazepine
flurbiprofen	nonsteroidal anti-inflammatory drug
flutamide	androgen receptor inhibitor
flutemetamol f-18	radioactive diagnostic agent
fluticasone	corticosteroid
fluvastatin	HMG CoA-reductase inhibitor
fluvoxamine	selective serotonin reuptake inhibitor (SSRI)
follitropin	gonadotropin
fomepizole	mucolytic antidote for acetaminophen overdose
fondaparinux	factor Xa inhibitor
fonsecaea pedrosoi	non-standardized fungal allergenic extract
foreskin fibroblast (neonatal)	allogeneic cultured cell scaffold
foreskin keratinocyte (neonatal)	allogeneic cultured cell scaffold
formaldehyde	standardized chemical allergen
formica exsectoides	non-standardized insect venom allergenic extract
formoterol	beta-2 adrenergic agonist
fosamprenavir	HIV protease inhibitor
foscarnet	pyrophosphate analog CMV DNA polymerase inhibitor / HSV DNA polymerase inhibitor
fosinopril	angiotensin converting enzyme inhibitor
fosinoprilat	angiotensin converting enzyme inhibitor
fraxinus americana pollen	non-standardized pollen allergenic extract
fraxinus excelsior pollen	non-standardized pollen allergenic extract
fraxinus latifolia pollen	non-standardized pollen allergenic extract
fraxinus nigra pollen	non-standardized pollen allergenic extract
fraxinus pennsylvanica pollen	non-standardized pollen allergenic extract

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	FDA Established Pharmacologic Class (EPC) Text Phrase
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Active Molety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
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	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
fraxinus velutina pollen	non-standardized pollen allergenic extract
frovatriptan	serotonin 5-HT1B/1D receptor agonist (triptan)
fulvestrant	estrogen receptor antagonist
furosemide	loop diuretic
fusarium compactum	non-standardized fungal allergenic extract
fusarium oxysporum	non-standardized fungal allergenic extract
fusarium oxysporum vasinfectum	non-standardized fungal allergenic extract
fusarium sporotrichioides	non-standardized fungal allergenic extract
gabapentin	antiepileptic drug (AED)
gadobenic acid	paramagnetic contrast agent
gadobutrol	gadolinium-based contrast agent
gadodiamide	paramagnetic contrast agent
gadofosveset	paramagnetic contrast agent
gadolinium cation (3+)	gadolinium-based contrast agent
gadopentetic acid	paramagnetic contrast agent
gadoteridol	paramagnetic contrast agent
gadoversetamide	paramagnetic contrast agent
gadoxetic acid	paramagnetic contrast agent
galantamine	cholinesterase inhibitor
gallium citrate ga-67	radioactive diagnostic agent
gallium nitrate	calcium resorption inhibitor
gallium nitrate anhydrous	calcium resorption inhibitor
gallus gallus feather	non-standardized feather allergenic extract
galsulfase	hydrolytic lysozomal glycosaminoglycan (GAG)-specific enzyme
ganciclovir	nucleoside analog antiviral
ganciclovir	nucleoside analog CMV DNA polymerase inhibitor

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	Use in the Highlights" MAPP 7400.13.
ganirelix	gonadotropin releasing hormone (GnRH) antagonist
garden cress	non-standardized food allergenic extract
garden cress	non-standardized plant allergenic extract
garlic	non-standardized food allergenic extract
garrya elliptica pollen	non-standardized pollen allergenic extract
gatifloxacin	quinolone antimicrobial
gatifloxacin anhydrous	quinolone antimicrobial
gefitinib	kinase inhibitor
gemcitabine	nucleoside metabolic inhibitor
gemfibrozil	peroxisome proliferator-activated receptor (PPAR) alpha agonist
gemifloxacin	quinolone antimicrobial
gemtuzumab ozogamicin	CD33-directed cytotoxin
gentamicin	aminoglycoside antibacterial
geotrichum candidum	non-standardized fungal allergenic extract
geraniol	standardized chemical allergen
gerbillus perpallidus hair	non-standardized animal hair allergenic extract
gibberella fujikuroi	non-standardized fungal allergenic extract
gibberella zeae	non-standardized fungal allergenic extract
ginger	non-standardized food allergenic extract
ginger	non-standardized plant allergenic extract
gleditsia triacanthos pollen	non-standardized pollen allergenic extract
glimepiride	sulfonylurea
gliocladium viride	non-standardized fungal allergenic extract
glipizide	sulfonylurea
glucagon	antihypoglycemic agent
glucagon	gastrointestinal motility inhibitor

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gluconolactone	urinary calculi dissolution agent
glucosulfone free acid	antimycobacterial
glutamine	amino acid
glyburide	sulfonylurea
glycerin	non-standardized Chemical allergen
glycopyrrolate	anticholinergic
glycopyrronium	anticholinergic
glycyrrhiza glabra	non-standardized food allergenic extract
glycyrrhiza glabra	non-standardized plant allergenic extract
goat milk	non-standardized food allergenic extract
gold	standardized chemical allergen
golimumab	tumor necrosis factor (TNF) blocker
goserelin	gonadotropin releasing hormone (GnRH) agonist
granisetron	serotonin-3 (5-HT3) receptor antagonist
grape	non-standardized food allergenic extract
grapefruit	non-standardized food allergenic extract
green bell pepper	non-standardized food allergenic extract
green olive	non-standardized food allergenic extract
green olive	non-standardized plant allergenic extract
grindelia ciliata pollen	non-standardized pollen allergenic extract
griseofulvin	tubulin inhibiting agent
gryllus assimilis	non-standardized insect allergenic extract
guanabenz	central alpha-2 adrenergic agonist
guanfacine	central alpha-2 adrenergic agonist
guanidine	acetylcholine releasing agent
haddock	non-standardized food allergenic extract

Active Moiety Name  haematonectria haematococca	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13. non-standardized fungal allergenic extract
haemophilus influenzae type b capsular polysaccharide meningococcal outer membrane protein conjugate antigen	inactivated Haemophilus influenzae B vaccine
haemophilus influenzae type b strain 1482 capsular polysaccharide tetanus toxoid conjugate antigen	inactivated Haemophilus influenzae B vaccine
haemophilus influenzae type b strain 20,752 capsular polysaccharide tetanus toxoid conjugate antigen	inactivated Haemophilus influenzae B vaccine
halcinonide	corticosteroid
halobetasol	corticosteroid
halofantrine	antimalarial
haloperidol	typical antipsychotic
hazelnut, unspecified	non-standardized food allergenic extract
helianthus annuus pollen	non-standardized pollen allergenic extract
helminthosporium solani	non-standardized fungal allergenic extract
heparin	anti-coagulant
heparin	unfractionated heparin
hepatitis a virus strain cr 326f antigen (formaldehyde inactivated)	inactivated hepatitis A virus vaccine
hepatitis a virus strain hm175 antigen (formaldehyde inactivated)	inactivated hepatitis A virus vaccine
hepatitis b virus hbsag surface protein antigen	inactivated hepatitis B virus vaccine
hepatitis b virus subtype adw hbsag surface protein antigen	inactivated hepatitis B virus vaccine

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
herring, unspecified	non-standardized food allergenic extract
hetastarch	plasma volume expander
hexachlorophene	antiseptic
hexagenia limbata	non-standardized insect allergenic extract
histrelin	gonadotropin releasing hormone (GnRH) agonist
holcus lanatus pollen	non-standardized pollen allergenic extract
homatropine	muscarinic agonist
honeydew melon	non-standardized food allergenic extract
hops	non-standardized food allergenic extract
hops	non-standardized plant allergenic extract
hordeum murinum pollen	non-standardized pollen allergenic extract
hordeum vulgare pollen	non-standardized pollen allergenic extract
horseradish	non-standardized food allergenic extract
horseradish	non-standardized plant allergenic extract
hortaea werneckii	non-standardized fungal allergenic extract
house dust	non-standardized house dust allergenic extract
human adenovirus b serotype 7 strain 55142	live human adenovirus type 7 vaccine
human adenovirus e serotype 4 strain cl- 68578	live human adenovirus type 4 vaccine
human albumin microspheres	ultrasound contrast agent
human botulinum neurotoxin a/b immune globulin	human immunoglobulin G
human c1-esterase inhibitor	human C1 esterase inhibitor
human cord blood hematopoietic progenitor cell	allogeneic cord blood hematopoietic progenitor cell therapy

	FDA Fetablish ad Dhammanalania Olasa (FDO) Tarri Dhaman
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
human cytomegalovirus immune globulin	human immunoglobulin G
human hepatitis b virus immune globulin	human immunoglobulin
human immunoglobulin g	human immunoglobulin G
human leucocyte-derived alpha interferons	interferon alpha
human papillomavirus type 11 l1 capsid protein antigen	inactivated human Papillomavirus vaccine
human papillomavirus type 16 l1 capsid protein antigen	inactivated human Papillomavirus vaccine
human papillomavirus type 18 l1 capsid protein antigen	inactivated human Papillomavirus vaccine
human papillomavirus type 6 l1 capsid protein antigen	inactivated human Papillomavirus vaccine
human rho(d) immune globulin	human immunoglobulin G
human rotavirus a type g1p(8) strain rix4414 live antigen	live attenuated Rotavirus vaccine
human rotavirus a type g1p7(5) strain wi79 live antigen	live Rotavirus vaccine
human rotavirus a type g2p7(5) strain sc2 live antigen	live Rotavirus vaccine
human rotavirus a type g3p7(5) strain wi78 live antigen	live Rotavirus vaccine
human rotavirus a type g4p7(5) strain brb live antigen	live Rotavirus vaccine
human rotavirus a type g6p1a(8) strain wi79 live antigen	live Rotavirus vaccine
human vaccinia virus immune globulin	human immunoglobulin G

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
humicola grisea	non-standardized fungal allergenic extract
humulus japonicus pollen	non-standardized pollen allergenic extract
humulus lupulus pollen	non-standardized pollen allergenic extract
hyaluronidase	endoglycosidase
hyaluronidase recombinant human	endoglycosidase
hyaluronidase, ovine	endoglycosidase
hydralazine	arteriolar vasodilator
hydrochlorothiazide	thiazide diuretic
hydrocodone	opioid agonist
hydrocortisone	corticosteroid
hydroflumethiazide	thiazide diuretic
hydromorphone	opioid agonist
hydroquinone	melanin synthesis inhibitor
hydroxocobalamin	mucolytic antidote for acetaminophen overdose
hydroxyamphetamine	adrenergic agonist
hydroxychloroquine	antirheumatic
hydroxycitronellal	standardized chemical allergen
hydroxyethyl starch 130/0.4	plasma volume expander
hydroxyprogesterone	progestin
hydroxypropyl cellulose	demulcent
hydroxyurea	antimetabolite
hydroxyzine	antihistamine
hypomyces perniciosus	non-standardized fungal allergenic extract
ibandronic acid	bisphosphonate
ibritumomab tiuxetan	CD20-directed radiotherapeutic antibody
ibrutinib	kinase inhibitor

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
ibuprofen	nonsteroidal anti-inflammatory drug
ibutilide	antiarrhythmic
icatibant	bradykinin B2 receptor antagonist
idarubicin	anthracycline topoisomerase inhibitor
idoxuridine	nucleoside analog antiviral
idursulfase	hydrolytic lysozomal glycosaminoglycan (GAG)-specific enzyme
ifosfamide	alkylating drug
iloperidone	atypical antipsychotic
iloprost	prostacycline
imatinib	kinase inhibitor
imidurea	standardized chemical allergen
imiglucerase	hydrolytic lysozomal glucocerebroside-specific enzyme
imipenem	penem antibacterial
imipenem anhydrous	penem antibacterial
imipramine	tricyclic antidepressant (TCA)
indapamide	thiazide-like diuretic
indian brown mustard seed	non-standardized food allergenic extract
indian brown mustard seed	non-standardized plant allergenic extract
indinavir anhydrous	HIV protease inhibitor
indium chloride in-111	radioactive diagnostic agent
indium in-111 oxyquinoline	radioactive diagnostic agent
indium in-111 pentetate disodium	radioactive diagnostic agent
indium in-111 pentetreotide	radioactive diagnostic agent
indocyanine green	diagnostic dye
indomethacin	nonsteroidal anti-inflammatory drug
infliximab	tumor necrosis factor (TNF) blocker

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
influenza a virus a/brisbane/59/2007(h1n1) antigen (propiolactone inactivated)	inactivated influenza A virus vaccine
influenza a virus a/brisbane/59/2007(h1n1) hemagglutinin antigen (propiolactone inactivated)	inactivated influenza A virus vaccine
influenza a virus a/california/7/2009 (h1n1) live(attenuated) antigen	live attenuated influenza A virus vaccine
influenza a virus a/california/7/2009 x-181 (h1n1) hemagglutinin antigen (propiolactone inactivated)	inactivated influenza A virus vaccine
influenza a virus a/perth/16/2009 (h3n2) live(attenuated) antigen	live attenuated influenza A virus vaccine
influenza a virus a/uruguay/716/2007 (h3n2) antigen (propiolactone inactivated)	inactivated influenza A virus vaccine
influenza a virus a/victoria/210/2009 x-187 (h3n2) antigen (formaldehyde inactivated)	inactivated influenza A virus vaccine
influenza a virus a/vietnam/1203/2004 (h5n1, clade 1) hemagglutinin antigen (formaldehyde inactivated)	inactivated influenza A virus vaccine
influenza b virus b/brisbane/60/2008 antigen (formaldehyde inactivated)	inactivated influenza B virus vaccine
influenza b virus b/brisbane/60/2008 antigen (propiolactone inactivated)	inactivated influenza B virus vaccine

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
influenza b virus b/brisbane/60/2008	
hemagglutinin antigen (propiolactone inactivated)	inactivated influenza B virus vaccine
ingenol mebutate	inducer of cell death
insulin aspart	insulin analog
insulin detemir	insulin analog
insulin glargine	insulin analog
insulin glulisine	insulin analog
insulin human	insulin
insulin lispro	insulin analog
interferon alfa-2a	interferon alpha
interferon alfa-2b	interferon alpha
interferon alfacon-1	interferon alpha
interferon beta-1a	recombinant human interferon beta
interferon beta-1b	recombinant human interferon beta
interferon gamma-1b	interferon gamma
iobenguane i-131	radioactive diagnostic agent
iobenguane sulfate i-123	radioactive diagnostic agent
iodide ion i-131	radioactive therapeutic agent
iodinated i-125 serum albumin	radioactive diagnostic agent
iodine i-123	radioactive diagnostic agent
iodipamide	radiographic contrast agent
iodixanol	radiographic contrast agent
iodohippurate sodium i-131	radioactive diagnostic agent
iodohippuric acid i-131	radioactive diagnostic agent
iohexol	radiographic contrast agent

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights  Indications and Usage heading if a drug is a member of an EPC [see 21 CFR  201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each  listed active moiety, the associated FDA EPC text phrase is included in this document.  For more information about how FDA determines the EPC Text Phrase, see the 2009  "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for  Use in the Highlights" MAPP 7400.13.
iopamidol	radiographic contrast agent
iopromide	radiographic contrast agent
iothalamate sodium, i-125	radioactive diagnostic agent
iothalamic acid	radiographic contrast agent
iothalamic acid i-125	radioactive diagnostic agent
ioversol	radiographic contrast agent
ioxaglic acid	radiographic contrast agent
ioxilan	radiographic contrast agent
ipilimumab	human cytotoxic T-lymphocyte antigen 4 (CTLA-4)-blocking antibody
ipratropium	anticholinergic
irbesartan	angiotensin II receptor blocker
irinotecan	topoisomerase inhibitor
iris germanica var. florentina root	non-standardized plant allergenic extract
iron sucrose	iron replacement product
isavuconazole	azole antifungal
isocarboxazid	monoamine oxidase inhibitor (MAOI)
isoeugenol	standardized chemical allergen
isoflurane	general anesthetic
isoniazid	antimycobacterial
isoproterenol	beta adrenergic agonist
isosorbide dinitrate	nitrate vasodilator
isosorbide mononitrate	nitrate vasodilator
isotretinoin	retinoid
isradipine	dihydropyridine calcium channel blocker
itraconazole	azole antifungal
iva angustifolia pollen	non-standardized pollen allergenic extract

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
iva annua pollen	non-standardized pollen allergenic extract
iva axillaris pollen	non-standardized pollen allergenic extract
ivacaftor	cystic fibrosis transmembrane conductance regulator (CFTR) potentiator
ivermectin	antiparasitic
ivermectin	pediculicide
ixabepilone	microtubule inhibitor
japanese encephalitis virus strain nakayama- nih antigen (formaldehyde inactivated)	inactivated Japanese encephalitis virus vaccine
japanese encephalitis virus strain sa 14-14-2 antigen (formaldehyde inactivated)	inactivated Japanese encephalitis virus vaccine
jerusalem artichoke	non-standardized food allergenic extract
jerusalem artichoke	non-standardized plant allergenic extract
juglans californica pollen	non-standardized pollen allergenic extract
juglans cinerea pollen	non-standardized pollen allergenic extract
juglans hindsii pollen	non-standardized pollen allergenic extract
juglans major pollen	non-standardized pollen allergenic extract
juglans microcarpa pollen	non-standardized pollen allergenic extract
juglans nigra pollen	non-standardized pollen allergenic extract
juglans regia pollen	non-standardized pollen allergenic extract
juniper berry	non-standardized food allergenic extract
juniper berry	non-standardized plant allergenic extract
juniperus ashei pollen	non-standardized pollen allergenic extract
juniperus californica pollen	non-standardized pollen allergenic extract
juniperus chinensis pollen	non-standardized pollen allergenic extract
juniperus monosperma pollen	non-standardized pollen allergenic extract

	EDA Establish ad Dhamasasla via Olasa (EDO) Taat Dhamas
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
juniperus occidentalis pollen	non-standardized pollen allergenic extract
juniperus osteosperma pollen	non-standardized pollen allergenic extract
juniperus pinchotii pollen	non-standardized pollen allergenic extract
juniperus scopulorum pollen	non-standardized pollen allergenic extract
juniperus virginiana pollen	non-standardized pollen allergenic extract
kanamycin	aminoglycoside antibacterial
karaya gum	non-standardized food allergenic extract
ketamine	general anesthetic
ketoconazole	azole antifungal
ketoprofen	nonsteroidal anti-inflammatory drug
ketorolac	nonsteroidal anti-inflammatory drug
ketotifen	histamine-1 (H1) inhibitor
khuskia oryzae	non-standardized fungal allergenic extract
kidney bean	non-standardized food allergenic extract
kidney bean	non-standardized plant allergenic extract
koeleria macrantha pollen	non-standardized pollen allergenic extract
krascheninnikovia lanata pollen	non-standardized pollen allergenic extract
labetalol	beta adrenergic blocker
laburnum anagyroides pollen	non-standardized pollen allergenic extract
lacosamide	antiepileptic drug (AED)
lactulose	osmotic laxative
lake trout	non-standardized food allergenic extract
lake whitefish	non-standardized food allergenic extract
lamb	non-standardized food allergenic extract
lamivudine	HBV nucleoside analog reverse transcriptase inhibitor (HBV-NRTI)
lamivudine	HIV nucleoside analog reverse transcriptase inhibitors (HIV NRTI)

	FDA Established Pharmacologic Class (EPC) Text Phrase
	PLR regulations require that the following statement is included in the Highlights
	Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
Active Moiety Name	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
,	listed active moiety, the associated FDA EPC text phrase is included in this document.
	For more information about how FDA determines the EPC Text Phrase, see the 2009
	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
lamotrigine	antiepileptic drug (AED)
lamotrigine	mood stabilizer
lanolin alcohols	standardized chemical allergen
lanreotide	somatostatin analog
lansoprazole	proton pump inhibitor
lanthanum cation (3+)	phosphate binder
lapatinib	kinase inhibitor
lapine t-lymphocyte immune globulin	immunoglobulin G
largemouth bass	non-standardized food allergenic extract
larix decidua pollen	non-standardized pollen allergenic extract
larix laricina pollen	non-standardized pollen allergenic extract
larix occidentalis pollen	non-standardized pollen allergenic extract
laronidase	hydrolytic lysozomal glycosaminoglycan (GAG)-specific enzyme
larrea tridentata pollen	non-standardized pollen allergenic extract
latanoprost	prostaglandin analog
lawsonia inermis leaf	non-standardized plant allergenic extract
ledipasvir	hepatitis C virus (HCV) NS5A inhibitor
leek	non-standardized food allergenic extract
leek	non-standardized plant allergenic extract
leflunomide	antirheumatic
lemon	non-standardized food allergenic extract
lenalidomide	thalidomide analog
lentil	non-standardized food allergenic extract
lentil	non-standardized plant allergenic extract
lenvatinib	kinase inhibitor
lepirudin	anti-coagulant

	FDA Fotablished Dharmacalagia Class (FDC) Tayt Dhress
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights  Indications and Usage heading if a drug is a member of an EPC [see 21 CFR  201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each  listed active moiety, the associated FDA EPC text phrase is included in this document.  For more information about how FDA determines the EPC Text Phrase, see the 2009  "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for  Use in the Highlights" MAPP 7400.13.
lepirudin	direct thrombin inhibitor
letrozole	aromatase inhibitor
lettuce	non-standardized food allergenic extract
leucanthemum vulgare pollen	non-standardized pollen allergenic extract
leucovorin	folate analog
leuprolide	gonadotropin releasing hormone (GnRH) agonist
levalbuterol	beta-2 adrenergic agonist
levobunolol	beta adrenergic blocker
levocarnitine	carnitine analog
levocetirizine	histamine-1 (H1) receptor antagonist
levodopa	aromatic amino acid decarboxylation inhibitor
levofloxacin	quinolone antimicrobial
levomilnacipran	serotonin and norepinephrine reuptake inhibitor (SNRI)
levonorgestrel	progestin
levonorgestrel	progestin-containing intrauterine device (IUD)
levorphanol	opioid agonist
levothyroxine	L-thyroxine (T4)
leymus condensatus pollen	non-standardized pollen allergenic extract
leymus triticoides pollen	non-standardized pollen allergenic extract
lidocaine	amide local anesthetic
lidocaine	antiarrhythmic
ligustrum lucidum pollen	non-standardized pollen allergenic extract
ligustrum vulgare pollen	non-standardized pollen allergenic extract
lima bean	non-standardized food allergenic extract
lime (citrus)	non-standardized food allergenic extract
linaclotide	guanylate cyclase-C agonist

	FDA Fetablished Dharmanalaria Class (FDC) Tayt Dhress
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights  Indications and Usage heading if a drug is a member of an EPC [see 21 CFR  201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each  listed active moiety, the associated FDA EPC text phrase is included in this document.  For more information about how FDA determines the EPC Text Phrase, see the 2009  "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for  Use in the Highlights" MAPP 7400.13.
linagliptin	dipeptidyl peptidase 4 (DPP-4) inhibitor
linezolid	oxazolidinone antibacterial
lingcod	non-standardized food allergenic extract
liothyronine	L-triiodothyronine (T3)
liotrix	L-thyroxine (T4)
liotrix	L-triiodothyronine (T3)
liquidambar styraciflua pollen	non-standardized pollen allergenic extract
liraglutide	GLP-1 receptor agonist
lisdexamfetamine	central nervous system stimulant
lisinopril	angiotensin converting enzyme inhibitor
lisinopril anhydrous	angiotensin converting enzyme inhibitor
lithium cation	mood stabilizer
lobster, unspecified	non-standardized food allergenic extract
lodoxamide	mast cell stabilizer
lolium multiflorum pollen	non-standardized pollen allergenic extract
lolium perenne pollen	standardized pollen allergenic extract
lomitapide	microsomal triglyceride transfer protein inhibitor
Iomustine	alkylating drug
loperamide	opioid agonist
lopinavir	HIV protease inhibitor
loracarbef	cephalosporin antibacterial
loracarbef anhydrous	cephalosporin antibacterial
lorazepam	benzodiazepine
lorcaserin	serotonin 2C receptor agonist
losartan	angiotensin II receptor blocker
loteprednol	corticosteroid

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
lovastatin	HMG CoA-reductase inhibitor
lubiprostone	chloride channel activator
luliconazole	azole antifungal
lumefantrine	antimalarial
lurasidone	atypical antipsychotic
lutropin alfa	gonadotropin
macaca mulatta dander	non-standardized animal dander allergenic extract
macaca mulatta hair	non-standardized animal hair allergenic extract
macalpinomyces neglectus	non-standardized fungal allergenic extract
mace	non-standardized food allergenic extract
mace	non-standardized plant allergenic extract
macitentan	endothelin receptor antagonist
maclura pomifera pollen	non-standardized pollen allergenic extract
mafenide	methylated sulfonamide antibacterial
magnesium cation	urinary calculi dissolution agent
malathion	cholinesterase inhibitor
malus domestica pollen	non-standardized pollen allergenic extract
mangafodipir	paramagnetic contrast agent
manganese cation (2+)	paramagnetic contrast agent
mango	non-standardized food allergenic extract
mannitol	osmotic diuretic
maraviroc	CCR5 co-receptor antagonist
measles virus strain enders' attenuated edmonston live antigen	live attenuated measles virus vaccine
mebendazole	anthelmintic
mecamylamine	autonomic ganglionic blocker

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
mechlorethamine	alkylating drug
meclizine	antiemetic
medicago sativa pollen	non-standardized pollen allergenic extract
medroxyprogesterone	progestin
medrysone	corticosteroid
mefenamic acid	nonsteroidal anti-inflammatory drug
mefloquine	antimalarial
megestrol	progestin
melaleuca quinquenervia pollen	non-standardized pollen allergenic extract
meleagris gallopavo feather	non-standardized feather allergenic extract
melica imperfecta pollen	non-standardized pollen allergenic extract
melica uniflora pollen	non-standardized pollen allergenic extract
melilotus albus pollen	non-standardized pollen allergenic extract
melilotus officinalis pollen	non-standardized pollen allergenic extract
melopsittacus undulatus feather	non-standardized feather allergenic extract
meloxicam	nonsteroidal anti-inflammatory drug
melphalan	alkylating drug
memantine	N-methyl-D-aspartate (NMDA) receptor antagonist
menotropins	gonadotropin
mepenzolate	anticholinergic
meperidine	opioid agonist
mephenytoin	antiepileptic drug (AED)
mepivacaine	amide local anesthetic
mequinol	skin lightening agent
mercaptopurine	nucleoside metabolic inhibitor
mercaptopurine anhydrous	nucleoside metabolic inhibitor

	FDA Fotablished Dharmacalagia Class (FDC) Tayt Dhress
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
meriones unguiculatus hair	non-standardized animal hair allergenic extract
meriones unguiculatus skin	non-standardized animal skin allergenic extract
meropenem	penem antibacterial
meropenem anhydrous	penem antibacterial
mesalamine	aminosalicylate
mesembryanthemum crystallinum pollen	non-standardized pollen allergenic extract
mesna	cytoprotective agent
mesocricetus auratus hair	non-standardized animal hair allergenic extract
mesocricetus auratus skin	non-standardized animal skin allergenic extract
mesoridazine	phenothiazine
mestranol	estrogen
metaproterenol	beta-2 adrenergic agonist
metaxalone	muscle relaxant
metformin	biguanide
methacholine	cholinergic agonist
methadone	opioid agonist
methamphetamine	amphetamine anorectic
methamphetamine	central nervous system stimulant
methimazole	thyroid hormone synthesis inhibitor
methocarbamol	muscle relaxant
methohexital	barbiturate
methotrexate	folate analog metabolic inhibitor
methoxsalen	photoactivated radical generator
methoxsalen	psoralen
methscopolamine	anticholinergic
methsuximide	antiepileptic drug (AED)

Active Moiety Name	PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
methyclothiazide	thiazide diuretic
methyl aminolevulinate	porphyrin precursor
methylchloroisothiazolinone	standardized chemical allergen
methyldibromo glutaronitrile	standardized chemical allergen
methyldopa	central alpha-2 adrenergic agonist
methyldopa anhydrous	central alpha-2 adrenergic agonist
methylergonovine	ergot derivative
methylnaltrexone	opioid antagonist
methylparaben	standardized chemical allergen
methylphenidate	central nervous system stimulant
methylprednisolone	corticosteroid
methyltestosterone	androgen
metipranolol	beta adrenergic blocker
metoclopramide	dopamine-2 (D2) antagonist
metolazone	thiazide-like diuretic
metoprolol	beta adrenergic blocker
metreleptin	leptin analog
metrizoic acid	radiographic contrast agent
metronidazole	nitroimidazole antimicrobial
metyrapone	adrenal steroid synthesis inhibitor
metyrosine	catecholamine synthesis inhibitor
mexiletine	antiarrhythmic
micafungin	echinocandin antifungal
miconazole	azole antifungal
microascus brevicaulis	non-standardized fungal allergenic extract
microsporum audouinii	non-standardized fungal allergenic extract

	FDA Fotablished Dharmanalaria Class (FDC) Toyt Dhyses
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
microsporum canis	non-standardized fungal allergenic extract
midazolam	benzodiazepine
midodrine	alpha adrenergic agonist
mifepristone	progestin antagonist
miglitol	alpha glucosidase inhibitor
miglustat	glucosylceramide synthase inhibitor
milium effusum pollen	non-standardized pollen allergenic extract
milnacipran	serotonin and norepinephrine reuptake inhibitor (SNRI)
milrinone	phosphodiesterase-3 inhibitor
miltefosine	antileishmanial drug
minocycline	tetracycline class drug
minoxidil	arteriolar vasodilator
mirabegron	beta-3 adrenergic agonist
misoprostol	prostaglandin-1 (PGE1) analog
mitomycin	alkylating drug
mitoxantrone	topoisomerase inhibitor
modafinil	sympathomimetic-like agent
moexipril	angiotensin converting enzyme inhibitor
moexiprilat	angiotensin converting enzyme inhibitor
mojave rattlesnake (crotalus scutulatus) immune fab antivenin (ovine)	antivenin
molindone	typical antipsychotic
mometasone	corticosteroid
monobenzone	depigmenting agent
monodictys castaneae	non-standardized fungal allergenic extract
monoethanolamine	sclerosing agent

	EDA Fataliliahad Dhammaadania Olaga (EDO) Taut Dhaga
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
monomorium minimum	non-standardized insect venom allergenic extract
monomorium pharaonis	non-standardized insect venom allergenic extract
montelukast	leukotriene receptor antagonist (LTRA)
morella cerifera pollen	non-standardized pollen allergenic extract
moricizine	antiarrhythmic
morphine	opioid agonist
morpholinylmercaptobenzothiazole	standardized chemical allergen
morus alba pollen	non-standardized pollen allergenic extract
morus rubra pollen	non-standardized pollen allergenic extract
moxifloxacin	quinolone antimicrobial
mucor circinelloides	non-standardized fungal allergenic extract
mucor circinelloides f. circinelloides	non-standardized fungal allergenic extract
mucor circinelloides f. lusitanicus	non-standardized fungal allergenic extract
mucor plumbeus	non-standardized fungal allergenic extract
mucor racemosus	non-standardized fungal allergenic extract
mumps virus strain b level jeryl lynn live antigen	live attenuated mumps virus vaccine
mung bean	non-standardized food allergenic extract
mung bean	non-standardized plant allergenic extract
mupirocin	RNA synthetase inhibitor antibacterial
muromonab-cd3	CD3 blocker immunosuppressant (antibody)
mus musculus hair	non-standardized animal hair allergenic extract
mus musculus skin	non-standardized animal skin allergenic extract
musca domestica	non-standardized insect allergenic extract
mustard greens	non-standardized food allergenic extract
mustard greens	non-standardized plant allergenic extract

	FDA Fatablishad Dhamasadania Olasa (FDO) Taut Dhamas
Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
mustard seed	non-standardized food allergenic extract
mustard seed	non-standardized plant allergenic extract
mycocladus corymbiferus	non-standardized fungal allergenic extract
mycophenolic acid	antimetabolite immunosuppressant
myrica gale pollen	non-standardized pollen allergenic extract
myrothecium verrucaria	non-standardized fungal allergenic extract
n,n'-diphenyl-1,4-phenylenediamine	standardized chemical allergen
nabilone	cannabinoid
nabumetone	nonsteroidal anti-inflammatory drug
nadolol	beta adrenergic blocker
nafarelin	gonadotropin releasing hormone (GnRH) agonist
nafcillin	penicillin class antibacterial
naftifine	allylamine antifungal
nalbuphine	opioid agonist/antagonist
nalmefene	opioid antagonist
naloxegol	opioid antagonist
naloxone	opioid antagonist
naltrexone	opioid antagonist
nandrolone	androgen
napa cabbage	non-standardized food allergenic extract
napa cabbage	non-standardized plant allergenic extract
naproxen	nonsteroidal anti-inflammatory drug
naratriptan	serotonin 5-HT1B/1D receptor agonist (triptan)
natalizumab	integrin receptor antagonist
natamycin	polyene antimicrobial
nateglinide	glinide

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
n-cyclohexyl-2-benzothiazosulfenamide	standardized chemical allergen
n-cyclohexyl-n'-phenyl-1,4-phenylenediamine	standardized chemical allergen
nedocromil	mast cell stabilizer
nefazodone	selective serotonin reuptake inhibitor (SSRI)
neisseria meningitidis group a capsular oligosaccharide diphtheria crm197 protein conjugate antigen	inactivated meningococcal vaccine
neisseria meningitidis group a capsular polysaccharide antigen	inactivated meningococcal vaccine
neisseria meningitidis group a capsular polysaccharide diphtheria toxoid conjugate antigen	inactivated meningococcal vaccine
neisseria meningitidis group c capsular oligosaccharide diphtheria crm197 protein conjugate antigen	inactivated meningococcal vaccine
neisseria meningitidis group c capsular polysaccharide antigen	inactivated meningococcal vaccine
antigen	inactivated meningococcal vaccine
conjugate antigen	inactivated meningococcal vaccine
neisseria meningitidis group w-135 capsular polysaccharide antigen	inactivated meningococcal vaccine

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
neisseria meningitidis group w-135 capsular polysaccharide diphtheria toxoid conjugate antigen	inactivated meningococcal vaccine
neisseria meningitidis group y capsular oligosaccharide diphtheria crm197 protein conjugate antigen	inactivated meningococcal vaccine
neisseria meningitidis group y capsular polysaccharide antigen	inactivated meningococcal vaccine
neisseria meningitidis group y capsular polysaccharide diphtheria toxoid conjugate antigen	inactivated meningococcal vaccine
nelarabine	nucleoside metabolic inhibitor
nelfinavir	HIV protease inhibitor
neomycin	aminoglycoside antibacterial
neostigmine	cholinesterase inhibitor
nepafenac	nonsteroidal anti-inflammatory drug
nesiritide	natriuretic peptide
netilmicin	aminoglycoside antibacterial
netupitant	substance P/neurokinin-1 (NK-1) receptor antagonist
neurospora intermedia	non-standardized fungal allergenic extract
neurospora sitophila	non-standardized fungal allergenic extract
nevirapine	HIV nonnucleoside analog reverse transcriptase inhibitor (HIV-1 NNRTI)
niacin	nicotinic acid
nicardipine	dihydropyridine calcium channel blocker
nickel	standardized chemical allergen
nicotine	nicotine agonist

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nifedipine	dihydropyridine calcium channel blocker
nilotinib	kinase inhibitor
nilutamide	androgen receptor inhibitor
nimodipine	dihydropyridine calcium channel blocker
nintedanib	kinase inhibitor
nisoldipine	dihydropyridine calcium channel blocker
n-isopropyl-n'-phenyl-1,4-phenylenediamine	standardized chemical allergen
nitazoxanide	antiprotozoal
nitisinone	hydroxyphenyl-pyruvate dioxygenase inhibitor
nitric oxide	vasodilator
nitrofurantoin	nitrofuran antibacterial
nitroglycerin	nitrate vasodilator
nivolumab	programmed death receptor-1 (PD-1)-blocking antibody
nizatidine	histamine-2 (H2) receptor antagonist
norelgestromin	progestin
norepinephrine	catecholamine
norethindrone	progestin
norfloxacin	quinolone antimicrobial
norgestimate	progestin
northern pike	non-standardized food allergenic extract
northern quahog	non-standardized food allergenic extract
nortriptyline	tricyclic antidepressant (TCA)
nutmeg	non-standardized food allergenic extract
nutmeg	non-standardized plant allergenic extract
nyssa sylvatica pollen	non-standardized pollen allergenic extract

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
nystatin	polyene antifungal
oat	non-standardized food allergenic extract
oatmeal	non-standardized food allergenic extract
oatmeal	non-standardized plant allergenic extract
obinutuzumab	CD20-directed cytolytic antibody
ocean perch, unspecified	non-standardized food allergenic extract
octreotide	somatostatin analog
ofatumumab	CD20-directed cytolytic antibody
ofloxacin	quinolone antimicrobial
okra	non-standardized food allergenic extract
okra	non-standardized plant allergenic extract
olanzapine	atypical antipsychotic
olea europaea pollen	non-standardized pollen allergenic extract
olmesartan	angiotensin II receptor blocker
olopatadine	histamine-1 (H1) inhibitor
olsalazine	aminosalicylate
omalizumab	anti-IgE
omega-3 fatty acids	omega-3 fatty acid
omeprazole	proton pump inhibitor
ondansetron	serotonin-3 (5-HT3) receptor antagonist
onion	non-standardized food allergenic extract
oprelvekin	megakaryocyte growth factor
opuntia x occidentalis pollen	non-standardized pollen allergenic extract
orange	non-standardized food allergenic extract
oregano	non-standardized food allergenic extract
orlistat	intestinal lipase inhibitor

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
orphenadrine	muscle relaxant
oryctolagus cuniculus hair	non-standardized animal hair allergenic extract
oryctolagus cuniculus skin	non-standardized animal skin allergenic extract
oseltamivir	influenza neuraminidase inhibitor (NAI)
ostrya virginiana pollen	non-standardized pollen allergenic extract
ovine digoxin immune fab	immunoglobulin G
oxacillin	penicillin class antibacterial
oxaliplatin	platinum-based drug
oxamniquine	anthelmintic
oxaprozin	nonsteroidal anti-inflammatory drug
oxazepam	benzodiazepine
oxcarbazepine	antiepileptic drug (AED)
oxiconazole	azole antifungal
oxybutynin	muscarinic antagonist
oxycodone	opioid agonist
oxymorphone	opioid agonist
oxytetracycline	tetracycline class antimicrobial
oxytetracycline anhydrous	tetracycline class antimicrobial
oxytocin	oxytocic
oyster, unspecified	non-standardized food allergenic extract
pacific halibut	non-standardized food allergenic extract
pacific sand sole	non-standardized food allergenic extract
paclitaxel	microtubule inhibitor
paecilomyces variotii	non-standardized fungal allergenic extract
painted comber	non-standardized food allergenic extract
palbociclib	kinase inhibitor

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
palifermin	mucocutaneous epithelial cell growth factor
paliperidone	atypical antipsychotic
palivizumab	RSV anti-F protein monoclonal (mAb)
palonosetron	serotonin-3 (5-HT3) receptor antagonist
pamidronic acid	bisphosphonate
pancuronium	nondepolarizing neuromuscular blocker
panicum miliaceum pollen	non-standardized pollen allergenic extract
panitumumab	epidermal growth factor receptor (EGFR) antagonist
panobinostat	histone deacetylase (HDAC) inhibitor
pantoprazole	proton pump inhibitor
papaya	non-standardized food allergenic extract
paprika	non-standardized food allergenic extract
parathyroid hormone	parathyroid hormone
paricalcitol	vitamin D3 analog
parietaria judaica pollen	non-standardized pollen allergenic extract
parietaria officinalis pollen	non-standardized pollen allergenic extract
parkinsonia florida pollen	non-standardized pollen allergenic extract
paromomycin	antiprotozoal
paroxetine	selective serotonin reuptake inhibitor (SSRI)
parsley	non-standardized food allergenic extract
parsnip	non-standardized food allergenic extract
parthenolide	standardized chemical allergen
pascopyrum smithii pollen	non-standardized pollen allergenic extract
pasireotide	somatostatin analog
paspalum dilatatum pollen	non-standardized pollen allergenic extract
paspalum distichum pollen	non-standardized pollen allergenic extract

Active Meioty Nome	FDA Established Pharmacologic Class (EPC) Text Phrase
	PLR regulations require that the following statement is included in the Highlights
	Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
Active Moiety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
	For more information about how FDA determines the EPC Text Phrase, see the 2009
	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
paspalum notatum pollen	non-standardized pollen allergenic extract
passalora fulva	non-standardized fungal allergenic extract
pazopanib	kinase inhibitor
pea	non-standardized food allergenic extract
peach	non-standardized food allergenic extract
peanut	non-standardized food allergenic extract
pear	non-standardized food allergenic extract
pearl millet	non-standardized food allergenic extract
pearl millet	non-standardized plant allergenic extract
pecan	non-standardized food allergenic extract
pegademase bovine	bovine intestinal adenosine deaminase
pegaspargase	asparagine-specific enzyme
pegfilgrastim	leukocyte growth factor
peginesatide	erythropoiesis-stimulating agent (ESA)
peginterferon alfa-2a	interferon alpha
peginterferon alfa-2b	interferon alpha
pegloticase	uric acid specific enzyme
pegvisomant	growth hormone receptor antagonist
pegzerepoetin alfa	erythropoiesis-stimulating agent (ESA)
pembrolizumab	human programmed death receptor-1 (PD-1)-blocking antibody
pemetrexed	folate analog metabolic inhibitor
pemirolast	mast cell stabilizer
penaeus shrimp	non-standardized food allergenic extract
penbutolol	beta adrenergic blocker
penciclovir	nucleoside analog HSV DNA polymerase inhibitor / VZV DNA polymerase inhibitor
penicillamine	antirheumatic

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
penicillin g	penicillin class antibacterial
penicillin v	penicillin class antibacterial
penicillium atramentosum	non-standardized fungal allergenic extract
penicillium camemberti	non-standardized fungal allergenic extract
penicillium carminoviolaceum	non-standardized fungal allergenic extract
penicillium chrysogenum var. chrysogenum	non-standardized fungal allergenic extract
penicillium digitatum	non-standardized fungal allergenic extract
penicillium expansum	non-standardized fungal allergenic extract
penicillium funiculosum	non-standardized fungal allergenic extract
penicillium glaucum	non-standardized food allergenic extract
penicillium glaucum	non-standardized fungal allergenic extract
penicillium italicum	non-standardized fungal allergenic extract
penicillium oxalicum	non-standardized fungal allergenic extract
penicillium roqueforti	non-standardized fungal allergenic extract
penicillium roseopurpureum	non-standardized fungal allergenic extract
penicillium rubrum	non-standardized fungal allergenic extract
penicillium simplicissimum	non-standardized fungal allergenic extract
penicillium westlingii	non-standardized fungal allergenic extract
pentamidine	antiprotozoal
pentastarch	plasma volume expander
pentazocine	partial opioid agonist/antagonist
pentetic acid	lead chelator
pentosan polysulfate	glycosaminoglycan
pentostatin	nucleoside metabolic inhibitor
pentoxifylline	blood viscosity reducer

Active Moiety Name	PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
peppermint	non-standardized food allergenic extract
peppermint	non-standardized plant allergenic extract
perampanel	non-competitive AMPA glutamate receptor antagonist
perch, unspecified	non-standardized food allergenic extract
perflexane	ultrasound contrast agent
perflutren	ultrasound contrast agent
pergolide	ergot-derived dopamine receptor agonist
perindopril	angiotensin converting enzyme inhibitor
perindoprilat	angiotensin converting enzyme inhibitor
periplaneta americana	non-standardized insect allergenic extract
periplaneta australasiae	non-standardized insect allergenic extract
permethrin	pyrethroid
perphenazine	phenothiazine
pertuzumab	HER2/neu receptor antagonist
phalaris arundinacea pollen	non-standardized pollen allergenic extract
phalaris californica pollen	non-standardized pollen allergenic extract
phalaris canariensis pollen	non-standardized pollen allergenic extract
phalaris caroliniana pollen	non-standardized pollen allergenic extract
phalaris minor pollen	non-standardized pollen allergenic extract
phalaris paradoxa pollen	non-standardized pollen allergenic extract
phasianus colchicus feather	non-standardized feather allergenic extract
phendimetrazine	sympathomimetic amine anorectic
phenelzine	monoamine oxidase inhibitor (MAOI)
phenoxybenzamine	alpha adrenergic blocker
phenprocoumon	vitamin K antagonist
phentermine	sympathomimetic amine anorectic

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
phentolamine	alpha adrenergic blocker
phenylacetic acid	nitrogen binding agent
phenylbutyric acid	nitrogen binding agent
phenylephrine	alpha-1 adrenergic receptor agonist
phenytoin	antiepileptic drug (AED)
philadelphus coronarius pollen	non-standardized pollen allergenic extract
philadelphus lewisii pollen	non-standardized pollen allergenic extract
phleum pratense pollen	standardized pollen allergenic extract
phoenix canariensis pollen	non-standardized pollen allergenic extract
phoenix dactylifera pollen	non-standardized pollen allergenic extract
phoma destructiva	non-standardized fungal allergenic extract
phoma exigua var. exigua	non-standardized fungal allergenic extract
phoma hibernica	non-standardized fungal allergenic extract
phosphate ion p-32	radioactive therapeutic agent
phragmites australis pollen	non-standardized pollen allergenic extract
phycomyces blakesleeanus	non-standardized fungal allergenic extract
phytonadione	vitamin K replacement
phytonadione	warfarin reversal agent
picea abies pollen	non-standardized pollen allergenic extract
picea engelmannii pollen	non-standardized pollen allergenic extract
picea pungens pollen	non-standardized pollen allergenic extract
picea rubens pollen	non-standardized pollen allergenic extract
picea sitchensis pollen	non-standardized pollen allergenic extract
pilocarpine	cholinergic agonist
pimecrolimus	calcineurin inhibitor immunosuppressant
pimozide	typical antipsychotic

	FDA Established Pharmacologic Class (EPC) Text Phrase
	PLR regulations require that the following statement is included in the Highlights
	Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
Active Meiety Neme	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
Active Moiety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
	For more information about how FDA determines the EPC Text Phrase, see the 2009
	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
pindolol	beta adrenergic blocker
pineapple	non-standardized food allergenic extract
pinus banksiana pollen	non-standardized pollen allergenic extract
pinus canariensis pollen	non-standardized pollen allergenic extract
pinus cembroides pollen	non-standardized pollen allergenic extract
pinus contorta pollen	non-standardized pollen allergenic extract
pinus densiflora pollen	non-standardized pollen allergenic extract
pinus echinata pollen	non-standardized pollen allergenic extract
pinus edulis pollen	non-standardized pollen allergenic extract
pinus elliottii pollen	non-standardized pollen allergenic extract
pinus monophylla pollen	non-standardized pollen allergenic extract
pinus monticola pollen	non-standardized pollen allergenic extract
pinus nigra pollen	non-standardized pollen allergenic extract
pinus palustris pollen	non-standardized pollen allergenic extract
pinus pinea pollen	non-standardized pollen allergenic extract
pinus ponderosa pollen	non-standardized pollen allergenic extract
pinus radiata pollen	non-standardized pollen allergenic extract
pinus resinosa pollen	non-standardized pollen allergenic extract
pinus rigida pollen	non-standardized pollen allergenic extract
pinus sabiniana pollen	non-standardized pollen allergenic extract
pinus strobus pollen	non-standardized pollen allergenic extract
pinus sylvestris pollen	non-standardized pollen allergenic extract
pinus taeda pollen	non-standardized pollen allergenic extract
pinus thunbergii pollen	non-standardized pollen allergenic extract
pinus virginiana pollen	non-standardized pollen allergenic extract
pioglitazone	peroxisome proliferator-activated receptor (PPAR) alpha agonist

Active Moiety Name	PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
pioglitazone	peroxisome proliferator-activated receptor (PPAR) gamma agonist
pioglitazone	thiazolidinedione
piperacillin	penicillin class antibacterial
piperacillin anhydrous	penicillin class antibacterial
pirbuterol	beta-2 adrenergic agonist
piroxicam	nonsteroidal anti-inflammatory drug
pistachio	non-standardized food allergenic extract
pitavastatin	HMG CoA-reductase inhibitor
plantago lanceolata pollen	non-standardized pollen allergenic extract
plantago major pollen	non-standardized pollen allergenic extract
platanus occidentalis pollen	non-standardized pollen allergenic extract
platanus orientalis pollen	non-standardized pollen allergenic extract
platanus racemosa pollen	non-standardized pollen allergenic extract
platanus wrightii pollen	non-standardized pollen allergenic extract
platanus x acerifolia pollen	non-standardized pollen allergenic extract
platycladus orientalis pollen	non-standardized pollen allergenic extract
pleospora betae	non-standardized fungal allergenic extract
pleospora herbarum	non-standardized fungal allergenic extract
pleospora tarda	non-standardized fungal allergenic extract
plerixafor	hematopoietic stem cell mobilizer
plum	non-standardized food allergenic extract
poa annua pollen	non-standardized pollen allergenic extract
poa compressa pollen	non-standardized pollen allergenic extract
poa fendleriana pollen	non-standardized pollen allergenic extract
poa palustris pollen	non-standardized pollen allergenic extract
poa pratensis pollen	standardized pollen allergenic extract

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
poa secunda pollen	non-standardized pollen allergenic extract
poa trivialis pollen	non-standardized pollen allergenic extract
pogonomyrmex rugosus	non-standardized insect venom allergenic extract
polidocanol	sclerosing agent
poliovirus type 1 antigen (formaldehyde inactivated)	inactivated poliovirus vaccine
poliovirus type 2 antigen (formaldehyde inactivated)	inactivated poliovirus vaccine
poliovirus type 3 antigen (formaldehyde inactivated)	inactivated poliovirus vaccine
polistes dominulus venom protein	standardized insect venom protein allergenic extract
polistes fuscatus venom protein	standardized insect venom protein allergenic extract
polyethylene glycol 3350	osmotic laxative
polymyxin b	polymixin class antibacterial
polythiazide	thiazide diuretic
pomalidomide	thalidomide analog
ponatinib	kinase inhibitor
poppy seed	non-standardized food allergenic extract
poppy seed	non-standardized plant allergenic extract
populus alba pollen	non-standardized pollen allergenic extract
populus balsamifera pollen	non-standardized pollen allergenic extract
populus deltoides pollen	non-standardized pollen allergenic extract
populus deltoides subsp. monilifera pollen	non-standardized pollen allergenic extract
populus deltoides subsp. wislizeni pollen	non-standardized pollen allergenic extract
populus fremontii pollen	non-standardized pollen allergenic extract

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populus nigra pollen	non-standardized pollen allergenic extract
populus tremula pollen	non-standardized pollen allergenic extract
populus tremuloides pollen	non-standardized pollen allergenic extract
populus trichocarpa pollen	non-standardized pollen allergenic extract
populus x canadensis pollen	non-standardized pollen allergenic extract
populus x canescens pollen	non-standardized pollen allergenic extract
poractant alfa	surfactant
porfimer	photoactivated radical generator
pork	non-standardized food allergenic extract
posaconazole	azole antifungal
potassium cation	potassium salt
potassium citrate	metabolic alkalinizer
potassium citrate anhydrous	metabolic alkalinizer
potato	non-standardized food allergenic extract
poultry	non-standardized food allergenic extract
povidone-iodine	antiseptic
p-phenylenediamine	standardized chemical allergen
pralatrexate	folate analog metabolic inhibitor
pralidoxime	cholinesterase reactivator
pramipexole	nonergot dopamine agonist
pramlintide	amylin analog
prasugrel	P2Y12 platelet inhibitor
pravastatin	HMG CoA-reductase inhibitor
praziquantel	anthelmintic
prazosin	alpha adrenergic blocker
prednicarbate	corticosteroid

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prednisolone	corticosteroid
prednisone	corticosteroid
prednisone anhydrous	corticosteroid
prilocaine	amide local anesthetic
primaquine	antimalarial
primidone	antiepileptic drug (AED)
procainamide	antiarrhythmic
procarbazine	alkylating drug
prochlorperazine	phenothiazine
procyclidine	anticholinergic
progesterone	progesterone
proguanil	antimalarial
promethazine	phenothiazine
propafenone	antiarrhythmic
propantheline	anticholinergic
proparacaine	local anesthetic
propofol	general anesthetic
propoxyphene	opioid agonist
propranolol	beta adrenergic blocker
propylparaben	standardized chemical allergen
propylthiouracil	thyroid hormone synthesis inhibitor
prosopis glandulosa pollen	non-standardized pollen allergenic extract
prosopis juliflora pollen	non-standardized pollen allergenic extract
prosopis pallida pollen	non-standardized pollen allergenic extract
protamine	heparin reversal agent
protein c	anti-coagulant anti-coagulant

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prothrombin	Use in the Highlights" MAPP 7400.13.
	blood coagulation factor
protriptyline	tricyclic antidepressant (TCA)
prune	non-standardized food allergenic extract
prunus armeniaca pollen	non-standardized pollen allergenic extract
prunus avium pollen	non-standardized pollen allergenic extract
prunus cerasus pollen	non-standardized pollen allergenic extract
prunus domestica pollen	non-standardized pollen allergenic extract
prunus dulcis pollen	non-standardized pollen allergenic extract
prunus persica pollen	non-standardized pollen allergenic extract
prunus serotina pollen	non-standardized pollen allergenic extract
pseudoephedrine	alpha adrenergic agonist
pseudoroegneria spicata pollen	non-standardized pollen allergenic extract
pseudotsuga menziesii pollen	non-standardized pollen allergenic extract
pteridium aquilinum pollen	non-standardized pollen allergenic extract
p-tert-butylphenol-formaldehyde resin (low molecular weight)	standardized chemical allergen
puccinia graminis	non-standardized fungal allergenic extract
puccinia striiformis var. striiformis	non-standardized fungal allergenic extract
pumpkin	non-standardized food allergenic extract
purshia tridentata pollen	non-standardized pollen allergenic extract
pyrazinamide	antimycobacterial
pyridostigmine	cholinesterase inhibitor
pyrimethamine	dihydrofolate reductase inhibitor antimalarial
pyrus communis pollen	non-standardized pollen allergenic extract
quahog, unspecified	non-standardized food allergenic extract
quaternium-15	standardized chemical allergen

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	Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
Active Moiety Name	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
There's includy Hamo	listed active moiety, the associated FDA EPC text phrase is included in this document.
	For more information about how FDA determines the EPC Text Phrase, see the 2009
	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
quazepam	benzodiazepine
quercus agrifolia pollen	non-standardized pollen allergenic extract
quercus alba pollen	non-standardized pollen allergenic extract
quercus arizonica pollen	non-standardized pollen allergenic extract
quercus chrysolepis pollen	non-standardized pollen allergenic extract
quercus coccinea pollen	non-standardized pollen allergenic extract
quercus douglasii pollen	non-standardized pollen allergenic extract
quercus dumosa pollen	non-standardized pollen allergenic extract
quercus emoryi pollen	non-standardized pollen allergenic extract
quercus engelmannii pollen	non-standardized pollen allergenic extract
quercus falcata pollen	non-standardized pollen allergenic extract
quercus gambelii pollen	non-standardized pollen allergenic extract
quercus garryana pollen	non-standardized pollen allergenic extract
quercus havardii pollen	non-standardized pollen allergenic extract
quercus ilex pollen	non-standardized pollen allergenic extract
quercus kelloggii pollen	non-standardized pollen allergenic extract
quercus lobata pollen	non-standardized pollen allergenic extract
quercus macrocarpa pollen	non-standardized pollen allergenic extract
quercus marilandica pollen	non-standardized pollen allergenic extract
quercus michauxii pollen	non-standardized pollen allergenic extract
quercus muehlenbergii pollen	non-standardized pollen allergenic extract
quercus nigra pollen	non-standardized pollen allergenic extract
quercus palmeri pollen	non-standardized pollen allergenic extract
quercus palustris pollen	non-standardized pollen allergenic extract
quercus phellos pollen	non-standardized pollen allergenic extract
quercus prinoides pollen	non-standardized pollen allergenic extract

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	Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
Active Moiety Name	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
Active Molety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
	For more information about how FDA determines the EPC Text Phrase, see the 2009
	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
quercus robur pollen	non-standardized pollen allergenic extract
quercus rubra pollen	non-standardized pollen allergenic extract
quercus stellata pollen	non-standardized pollen allergenic extract
quercus suber pollen	non-standardized pollen allergenic extract
quercus velutina pollen	non-standardized pollen allergenic extract
quercus virginiana pollen	non-standardized pollen allergenic extract
quercus wislizeni pollen	non-standardized pollen allergenic extract
quetiapine	atypical antipsychotic
quinaprilat	angiotensin converting enzyme inhibitor
quince	non-standardized food allergenic extract
quinidine	antiarrhythmic
quinidine	CYP450 2D6 inhibitor
quinine	antimalarial
quinupristin	streptogramin antibacterial
rabbit	non-standardized food allergenic extract
rabeprazole	proton pump inhibitor
rabies virus strain flury lep antigen	inactivated rabies virus vaccine
(propiolactone inactivated)	Indetivated rabies viras vaccine
rabies virus strain kissling antigen	inactivated rabies virus vaccine
(propiolactone inactivated)	
rabies virus strain pm-1503-3m antigen	inactivated rabies virus vaccine
(propiolactone inactivated)	
radish	non-standardized food allergenic extract
radium ra-223 cation	alpha particle-emitting radioactive therapeutic agent
raloxifene	estrogen agonist/antagonist
raltegravir	HIV integrase strand transfer inhibitor (HIV-1 INSTI)

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ramelteon	melatonin receptor agonist
ramiprilat	angiotensin converting enzyme inhibitor
ramucirumab	human vascular endothelial growth factor receptor 2 (VEGFR2) antagonist
ranibizumab	vascular endothelial growth factor (VEGF) directed antibody
ranitidine	histamine-2 (H2) receptor antagonist
ranolazine	antianginal
ranunculus bulbosus pollen	non-standardized pollen allergenic extract
ranunculus repens pollen	non-standardized pollen allergenic extract
rasagiline	monoamine oxidase inhibitor (MAOI)
rasburicase	uric acid specific enzyme
raspberry	non-standardized food allergenic extract
rattus norvegicus hair	non-standardized animal hair allergenic extract
rattus norvegicus skin	non-standardized animal skin allergenic extract
red currant	non-standardized food allergenic extract
red currant	non-standardized plant allergenic extract
red pepper	non-standardized food allergenic extract
red snapper	non-standardized food allergenic extract
regadenoson	adenosine receptor agonist
regadenoson anhydrous	adenosine receptor agonist
regorafenib	kinase inhibitor
remifentanil	opioid agonist
repaglinide	glinide
reserpine	catecholamine-depleting sympatholytic
retapamulin	pleuromutilin antibacterial
rhizopus arrhizus var. arrhizus	non-standardized fungal allergenic extract

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rhizopus microsporus var. rhizopodiformis	non-standardized fungal allergenic extract
rhizopus stolonifer	non-standardized fungal allergenic extract
rhodotorula mucilaginosa	non-standardized fungal allergenic extract
rhodotorula rubra	non-standardized fungal allergenic extract
rhubarb	non-standardized food allergenic extract
rhubarb	non-standardized plant allergenic extract
rhus copallinum pollen	non-standardized pollen allergenic extract
ribavirin	nucleoside analog antiviral
rice	non-standardized food allergenic extract
ricinus communis pollen	non-standardized pollen allergenic extract
rifabutin	rifamycin antimycobacterial
rifampin	rifamycin antibacterial
rifapentine	rifamycin antimycobacterial
rifaximin	rifamycin antibacterial
rilpivirine	HIV nonnucleoside analog reverse transcriptase inhibitor (HIV-1 NNRTI)
riluzole	benzothiazole
rimabotulinumtoxinb	acetylcholine release inhibitor
rimantadine	influenza A M2 protein inhibitor
rimexolone	corticosteroid
riociguat	soluble guanylate cyclase (sGC) stimulator
ripe bell pepper	non-standardized food allergenic extract
risedronic acid	bisphosphonate
risperidone	atypical antipsychotic
ritonavir	HIV protease inhibitor
rituximab	CD20-directed cytolytic antibody

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Active Moiety Name	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
Active Molety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
	For more information about how FDA determines the EPC Text Phrase, see the 2009
	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
rivaroxaban	factor Xa inhibitor
rivastigmine	cholinesterase inhibitor
rizatriptan	serotonin 5-HT1B/1D receptor agonist (triptan)
robinia pseudoacacia pollen	non-standardized pollen allergenic extract
rocuronium	nondepolarizing neuromuscular blocker
roflumilast	phosphodiesterase 4 inhibitor
romidepsin	histone deacetylase (HDAC) inhibitor
romiplostim	thrombopoietin receptor agonist
ropinirole	nonergot dopamine agonist
ropivacaine	amide local anesthetic
rosiglitazone	peroxisome proliferator-activated receptor (PPAR) gamma agonist
rosiglitazone	thiazolidinedione
rosin	standardized chemical allergen
rosuvastatin	HMG CoA-reductase inhibitor
round whitefish	non-standardized food allergenic extract
rubella virus strain wistar ra 27/3 live antigen	live attenuated rubella virus vaccine
rubidium cation rb-82	radioactive diagnostic agent
rubidium chloride rb-82	radioactive diagnostic agent
rumex acetosella pollen	non-standardized pollen allergenic extract
rumex altissimus pollen	non-standardized pollen allergenic extract
rumex conglomeratus pollen	non-standardized pollen allergenic extract
rumex crispus pollen	non-standardized pollen allergenic extract
rumex mexicanus pollen	non-standardized pollen allergenic extract
rumex obtusifolius pollen	non-standardized pollen allergenic extract
rutabaga	non-standardized food allergenic extract

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rutabaga ruxolitinib	non-standardized plant allergenic extract kinase inhibitor
	non-standardized food allergenic extract
rye saccharomyces cerevisiae	non-standardized food allergenic extract
saccharomyces cerevisiae	non-standardized fungal allergenic extract
sacrosidase	sucrose specific enzyme
safflower seed	non-standardized food allergenic extract
safflower seed	non-standardized plant allergenic extract
sage	non-standardized food allergenic extract
sage	non-standardized plant allergenic extract
salicornia depressa pollen	non-standardized pollen allergenic extract
salix alba pollen	non-standardized pollen allergenic extract
salix babylonica pollen	non-standardized pollen allergenic extract
salix caprea pollen	non-standardized pollen allergenic extract
salix discolor pollen	non-standardized pollen allergenic extract
salix interior pollen	non-standardized pollen allergenic extract
salix laevigata pollen	non-standardized pollen allergenic extract
salix lasiolepis pollen	non-standardized pollen allergenic extract
salix lucida subsp. lasiandra pollen	non-standardized pollen allergenic extract
salix lutea pollen	non-standardized pollen allergenic extract
salix nigra pollen	non-standardized pollen allergenic extract
salix repens pollen	non-standardized pollen allergenic extract
salix sessilifolia pollen	non-standardized pollen allergenic extract
salmeterol	beta-2 adrenergic agonist
salmon, unspecified	non-standardized food allergenic extract

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Active Molety Name	listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
salmonella typhi ty2 vi polysaccharide antigen	inactivated Salmonella typhi vaccine
salmonella typhi ty21a live antigen	inactivated Salmonella typhi vaccine
salsola kali pollen	non-standardized pollen allergenic extract
salsola tragus pollen	non-standardized pollen allergenic extract
samarium sm-153 lexidronam pentasodium	radioactive therapeutic agent
sambucus nigra pollen	non-standardized pollen allergenic extract
sambucus nigra subsp. cerulea pollen	non-standardized pollen allergenic extract
sapropterin	phenylalanine hydroxylase activator
saquinavir	HIV protease inhibitor
sarcobatus vermiculatus pollen	non-standardized pollen allergenic extract
sarcocornia perennis pollen	non-standardized pollen allergenic extract
sargramostim	leukocyte growth factor
saxagliptin anhydrous	dipeptidyl peptidase 4 (DPP-4) inhibitor
scabiosa atropurpurea pollen	non-standardized pollen allergenic extract
scallop, unspecified	non-standardized food allergenic extract
schedonorus arundinaceus pollen	non-standardized pollen allergenic extract
schinus molle pollen	non-standardized pollen allergenic extract
schinus terebinthifolius pollen	non-standardized pollen allergenic extract
scopolamine	anticholinergic
sea scallop	non-standardized food allergenic extract
secale cereale pollen	non-standardized pollen allergenic extract
secretin	secretin class hormone
selegiline	monoamine oxidase inhibitor (MAOI)
selegiline	monoamine oxidase type B (MAO-B) inhibitor

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Active Moiety Name	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
Active Molety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
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	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
sequoia sempervirens pollen	non-standardized pollen allergenic extract
serinus canaria feather	non-standardized feather allergenic extract
sertaconazole	azole antifungal
sertraline	selective serotonin reuptake inhibitor (SSRI)
sesame seed	non-standardized food allergenic extract
setaria italica pollen	non-standardized pollen allergenic extract
sevelamer	phosphate binder
sevoflurane	general anesthetic
shrimp, unspecified	non-standardized food allergenic extract
sibutramine	norepinephrine, serotonin, and dopamine reuptake inhibitor anorectic
sildenafil	phosphodiesterase-5 (PDE-5) inhibitor
silodosin	alpha adrenergic blocker
siltuximab	interleukin-6 (IL-6) antagonist
silver sulfadiazine	sulfonamide antibacterial
simeprevir	hepatitis C virus (HCV) NS3/4A protease inhibitor
simvastatin	HMG CoA-reductase inhibitor
sinapis alba pollen	non-standardized pollen allergenic extract
sinapis arvensis pollen	non-standardized pollen allergenic extract
sincalide	cholecystokinin (CCK) analog
sipuleucel-t	autologous cellular immunotherapy
sirolimus	mTor inhibitor immunosuppressant
sitagliptin	dipeptidyl peptidase 4 (DPP-4) inhibitor
sodium chromate cr-51	radioactive diagnostic agent
sodium ferric gluconate complex	iron replacement product
sodium fluoride f-18	radioactive diagnostic agent
sodium iodide i-123	radioactive diagnostic agent

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sodium iodide i-131	radioactive therapeutic agent
sodium oxybate	central nervous system depressant
sodium phosphate p-32	radioactive therapeutic agent
sodium polystyrene sulfonate	potassium binder
softshell clam	non-standardized food allergenic extract
solenopsis geminata	non-standardized insect venom allergenic extract
solenopsis invicta	non-standardized insect venom allergenic extract
solenopsis richteri	non-standardized insect venom allergenic extract
solidago canadensis pollen	non-standardized pollen allergenic extract
solidago virgaurea pollen	non-standardized pollen allergenic extract
solifenacin	muscarinic antagonist
somatropin	recombinant human growth hormone
sorafenib	kinase inhibitor
sorghum bicolor pollen	non-standardized pollen allergenic extract
sorghum halepense pollen	non-standardized pollen allergenic extract
sorghum x drummondii pollen	non-standardized pollen allergenic extract
sotalol	antiarrhythmic
sour cherry	non-standardized food allergenic extract
sour cherry	non-standardized plant allergenic extract
soybean	non-standardized food allergenic extract
spearmint	non-standardized food allergenic extract
spinach	non-standardized food allergenic extract
spinosad	pediculicide
spironolactone	aldosterone antagonist
sporisorium cruentum	non-standardized fungal allergenic extract
sporisorium sorghi	non-standardized fungal allergenic extract

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sporobolus airoides pollen	non-standardized pollen allergenic extract
sporotrichum pruinosum	non-standardized fungal allergenic extract
spotted seatrout	non-standardized food allergenic extract
squash	non-standardized food allergenic extract
stachybotrys chartarum	non-standardized fungal allergenic extract
stavudine	HIV nucleoside analog reverse transcriptase inhibitors (HIV NRTI)
stemphylium sarciniforme	non-standardized fungal allergenic extract
stemphylium solani	non-standardized fungal allergenic extract
stipa lemmonii pollen	non-standardized pollen allergenic extract
stipa lepida pollen	non-standardized pollen allergenic extract
strawberry	non-standardized food allergenic extract
streptococcus pneumoniae type 1 capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 1 capsular polysaccharide diphtheria crm197 protein conjugate antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 10a capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 11a capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 12f capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 14 capsular polysaccharide antigen	inactivated pneumococcal vaccine

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streptococcus pneumoniae type 14 capsular polysaccharide diphtheria crm197 protein conjugate antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 15b capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 17f capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 18c capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 18c capsular polysaccharide diphtheria crm197 protein conjugate antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 19a capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 19a capsular polysaccharide diphtheria crm197 protein conjugate antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 19f capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 19f capsular polysaccharide diphtheria crm197 protein conjugate antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 2 capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 20 capsular polysaccharide antigen	inactivated pneumococcal vaccine

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
streptococcus pneumoniae type 22f capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 23f capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 23f capsular polysaccharide diphtheria crm197 protein conjugate antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 3 capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 3 capsular polysaccharide diphtheria crm197 protein conjugate antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 33f capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 4 capsular polysaccharide antigen	inactivated pneumococcal vaccine
conjugate antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 5 capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 5 capsular polysaccharide diphtheria crm197 protein conjugate antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 6a capsular polysaccharide diphtheria crm197 protein conjugate antigen	inactivated pneumococcal vaccine

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
streptococcus pneumoniae type 6b capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 6b capsular polysaccharide diphtheria crm197 protein conjugate antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 7f capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 7f capsular polysaccharide diphtheria crm197 protein conjugate antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 8 capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 9n capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 9v capsular polysaccharide antigen	inactivated pneumococcal vaccine
streptococcus pneumoniae type 9v capsular polysaccharide diphtheria crm197 protein conjugate antigen	inactivated pneumococcal vaccine
streptomyces griseus	non-standardized bacterial allergenic extract
streptomycin	aminoglycoside antibacterial
streptomycin	antimycobacterial
streptozocin	alkylating drug
string bean	non-standardized food allergenic extract
strontium cation sr-89	radioactive therapeutic agent
strontium chloride sr-89	radioactive therapeutic agent
strychnos nux-vomica seed	non-standardized plant allergenic extract

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights  Indications and Usage heading if a drug is a member of an EPC [see 21 CFR  201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each  listed active moiety, the associated FDA EPC text phrase is included in this document.  For more information about how FDA determines the EPC Text Phrase, see the 2009  "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for  Use in the Highlights" MAPP 7400.13.
suaeda californica pollen	non-standardized pollen allergenic extract
suaeda nigra pollen	non-standardized pollen allergenic extract
suaeda occidentalis pollen	non-standardized pollen allergenic extract
succimer	lead chelator
succinylcholine	depolarizing neuromuscular blocker
sucralfate	aluminum complex
sufentanil	opioid agonist
sulbactam	beta lactamase inhibitor
sulconazole	azole antifungal
sulfacetamide	sulfonamide antibacterial
sulfadiazine	sulfonamide antibacterial
sulfadoxine	sulfonamide
sulfamethoxazole	sulfonamide antimicrobial
sulfasalazine	aminosalicylate
sulfisoxazole	sulfonamide antimicrobial
sulindac	nonsteroidal anti-inflammatory drug
sumatriptan	serotonin 5-HT1B/1D receptor agonist (triptan)
summer squash	non-standardized food allergenic extract
sunflower seed	non-standardized food allergenic extract
sunitinib	kinase inhibitor
sus scrofa hair	non-standardized animal hair allergenic extract
sus scrofa skin	non-standardized animal skin allergenic extract
suvorexant	orexin receptor antagonist
sweet potato	non-standardized food allergenic extract
swordfish	non-standardized food allergenic extract
syagrus romanzoffiana pollen	non-standardized pollen allergenic extract

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase
	PLR regulations require that the following statement is included in the Highlights
	Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
Active Molety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
	For more information about how FDA determines the EPC Text Phrase, see the 2009
	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
syncephalastrum racemosum	non-standardized fungal allergenic extract
syringa vulgaris pollen	non-standardized pollen allergenic extract
tabanus nigrovittatus	non-standardized insect allergenic extract
tacrine	cholinesterase inhibitor
tacrolimus	calcineurin inhibitor immunosuppressant
tacrolimus anhydrous	calcineurin inhibitor immunosuppressant
tadalafil	phosphodiesterase-5 (PDE-5) inhibitor
tafluprost	prostaglandin analog
tagetes patula flowering top	non-standardized plant allergenic extract
talaromyces flavus	non-standardized fungal allergenic extract
talaromyces luteus	non-standardized fungal allergenic extract
taliglucerase alfa	hydrolytic lysosomal glucocerebroside-specific enzyme
tamarix gallica pollen	non-standardized pollen allergenic extract
tamoxifen	estrogen agonist/antagonist
tamsulosin	alpha adrenergic blocker
tanacetum cinerariifolium flower	non-standardized plant allergenic extract
tanacetum parthenium pollen	non-standardized pollen allergenic extract
tanacetum vulgare pollen	non-standardized pollen allergenic extract
tangerine	non-standardized food allergenic extract
tapentadol	opioid agonist
taraxacum officinale pollen	non-standardized pollen allergenic extract
tasimelteon	melatonin receptor agonist
tavaborole	oxaborole antifungal
taxodium distichum pollen	non-standardized pollen allergenic extract
taxodium mucronatum pollen	non-standardized pollen allergenic extract
taxus baccata pollen	non-standardized pollen allergenic extract

	FDA Fatall'ala di Diagnosa ala si'a Olaga (FDO) Tant Diagnosa
	FDA Established Pharmacologic Class (EPC) Text Phrase
	PLR regulations require that the following statement is included in the Highlights
	Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
Active Moiety Name	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
/ tours moisty runns	listed active moiety, the associated FDA EPC text phrase is included in this document.
	For more information about how FDA determines the EPC Text Phrase, see the 2009
	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
tazarotene	retinoid
tazobactam	beta lactamase inhibitor
tea leaf	non-standardized food allergenic extract
tea leaf	non-standardized plant allergenic extract
technetium tc-99m albumin	radioactive diagnostic agent
technetium tc-99m albumin aggregated	radioactive diagnostic agent
technetium tc-99m apcitide	radioactive diagnostic agent
technetium tc-99m bicisate	radioactive diagnostic agent
technetium tc-99m depreotide	radioactive diagnostic agent
technetium tc-99m disofenin	radioactive diagnostic agent
technetium tc-99m exametazime	radioactive diagnostic agent
technetium tc-99m gluceptate	radioactive diagnostic agent
technetium tc-99m mebrofenin	radioactive diagnostic agent
technetium tc-99m medronate	radioactive diagnostic agent
technetium tc-99m mertiatide	radioactive diagnostic agent
technetium tc-99m oxidronate	radioactive diagnostic agent
technetium tc-99m pentetate	radioactive diagnostic agent
technetium tc-99m pyrophosphate	radioactive diagnostic agent
technetium tc-99m red blood cells	radioactive diagnostic agent
technetium tc-99m sestamibi	radioactive diagnostic agent
technetium tc-99m sodium pertechnetate	radioactive diagnostic agent
technetium tc-99m succimer	radioactive diagnostic agent
technetium tc-99m sulfur colloid	radioactive diagnostic agent
technetium tc-99m teboroxime	radioactive diagnostic agent
technetium tc-99m tetrofosmin	radioactive diagnostic agent
technetium tc-99m tilmanocept	radioactive diagnostic agent

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
tedizolid	oxazolidinone antibacterial
tegaserod	serotonin-4 (5-HT4) receptor antagonist
telaprevir	hepatitis C virus (HCV) NS3/4A protease inhibitor
telbivudine	HBV nucleoside analog reverse transcriptase inhibitor (HBV-NRTI)
telithromycin	ketolide antibacterial
telmisartan	angiotensin II receptor blocker
temazepam	benzodiazepine
temozolomide	alkylating drug
temsirolimus	kinase inhibitor
teniposide	topoisomerase inhibitor
tenofovir	HBV nucleoside analog reverse transcriptase inhibitor (HBV-NRTI)
tenofovir	HIV nucleoside analog reverse transcriptase inhibitors (HIV NRTI)
tenofovir anhydrous	HBV nucleoside analog reverse transcriptase inhibitor (HBV-NRTI)
tenofovir anhydrous	HIV nucleoside analog reverse transcriptase inhibitors (HIV NRTI)
terazosin	alpha adrenergic blocker
terbinafine	allylamine antifungal
terconazole	azole antifungal
teriflunomide	pyrimidine synthesis inhibitor
teriparatide	parathyroid hormone analog
tesamorelin	growth hormone releasing factor (GRG) analog
testolactone	aromatase inhibitor
testosterone	androgen
tetrabenazine	vesicular monoamine transporter 2 (VMAT2) inhibitor
tetracaine	ester local anesthetic
tetracoccosporium paxianum	non-standardized fungal allergenic extract
tetracycline	tetracycline class antimicrobial

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
tetramethylthiuram monosulfide	standardized chemical allergen
thallous cation tl-201	radioactive diagnostic agent
thallous chloride tl-201	radioactive diagnostic agent
theophylline	methylxanthine
theophylline anhydrous	methylxanthine
thiabendazole	anthelmintic
thimerosal	standardized chemical allergen
thinopyrum ponticum pollen	non-standardized pollen allergenic extract
thioguanine	antimetabolite
thioguanine anhydrous	antimetabolite
thioridazine	phenothiazine
thiosulfuric acid	antidote
thiotepa	alkylating drug
thiothixene	typical antipsychotic
thiram	standardized chemical allergen
thrombin	blood coagulation factor
thrombin alfa	blood coagulation factor
thrombin human	human blood coagulation factor
thuja occidentalis pollen	non-standardized pollen allergenic extract
thuja plicata pollen	non-standardized pollen allergenic extract
thyme	non-standardized food allergenic extract
thyrotropin alfa	thyroid stimulating hormone
tiagabine	antiepileptic drug (AED)
ticagrelor	P2Y12 platelet inhibitor
ticarcillin	penicillin class antibacterial
ticlopidine	platelet aggregation inhibitor

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Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights  Indications and Usage heading if a drug is a member of an EPC [see 21 CFR  201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each  listed active moiety, the associated FDA EPC text phrase is included in this document.  For more information about how FDA determines the EPC Text Phrase, see the 2009  "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for  Use in the Highlights" MAPP 7400.13.
tigecycline	tetracycline class antibacterial
tilia americana pollen	non-standardized pollen allergenic extract
tilia cordata pollen	non-standardized pollen allergenic extract
tilia x europaea pollen	non-standardized pollen allergenic extract
tilletia caries	non-standardized fungal allergenic extract
tilletia controversa	non-standardized fungal allergenic extract
tiludronic acid	bisphosphonate
timolol	beta adrenergic blocker
timolol anhydrous	beta adrenergic blocker
tinidazole	nitroimidazole antimicrobial
tinzaparin	low molecular weight heparin (LMWH)
tioconazole	azole antifungal
tiopronin	reducing and complexing thiol
tiotropium	anticholinergic
tipranavir	HIV protease inhibitor
tirofiban	platelet aggregation inhibitor
tixocortol pivalate	standardized chemical allergen
tizanidine	central alpha-2 adrenergic agonist
tobacco leaf	non-standardized plant allergenic extract
tobramycin	aminoglycoside antibacterial
tocilizumab	interleukin-6 (IL-6) receptor antagonist
tofacitinib	Janus kinase (JAK) inhibitor
tolazamide	sulfonylurea
tolbutamide	sulfonylurea
tolcapone	catechol o-methyl transferase (COMT) inhibitor
tolmetin	nonsteroidal anti-inflammatory drug

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
tolterodine	muscarinic antagonist
tomato	non-standardized food allergenic extract
topotecan	topoisomerase inhibitor
toremifene	estrogen agonist/antagonist
torsemide	loop diuretic
tositumomab	CD20-directed radiotherapeutic antibody
tositumomab i-131	CD20-directed radiotherapeutic antibody
tragacanth	non-standardized food allergenic extract
tragacanth	non-standardized plant allergenic extract
tramadol	opioid agonist
trametinib	kinase inhibitor
trandolapril	angiotensin converting enzyme inhibitor
trandolaprilat	angiotensin converting enzyme inhibitor
tranexamic acid	antifibrinolytic
tranylcypromine	monoamine oxidase inhibitor (MAOI)
trastuzumab	HER2 receptor antagonist
travoprost	prostaglandin analog
trazodone	selective serotonin reuptake inhibitor (SSRI)
treprostinil	prostacycline vasodilator
tretinoin	retinoid
triamcinolone	corticosteroid
triamterene	potassium-sparing diuretic
triazolam	benzodiazepine
trichoderma harzianum	non-standardized fungal allergenic extract
trichoderma viride	non-standardized fungal allergenic extract
trichophyton mentagrophytes	non-standardized fungal allergenic extract

Active Moiety Name  trichophyton rubrum	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document.  For more information about how FDA determines the EPC Text Phrase, see the 2009  "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.  non-standardized fungal allergenic extract
trichophyton schoenleinii	non-standardized fungal allergenic extract
trichophyton tonsurans	non-standardized fungal allergenic extract
trichothecium roseum	non-standardized fungal allergenic extract
trientine	metal chelator
trifluoperazine	phenothiazine
trifluridine	nucleoside analog antiviral
trifolium hybridum pollen	non-standardized pollen allergenic extract
trifolium pratense pollen	non-standardized pollen allergenic extract
trifolium repens pollen	non-standardized pollen allergenic extract
trimethadione	antiepileptic drug (AED)
trimethobenzamide	antiemetic
trimethoprim	dihydrofolate reductase inhibitor antibacterial
trimipramine	tricyclic antidepressant (TCA)
trioxsalen	psoralen
tripleurospermum inodorum pollen	non-standardized pollen allergenic extract
tripsacum dactyloides pollen	non-standardized pollen allergenic extract
triptorelin	gonadotropin releasing hormone (GnRH) agonist
trithrinax brasiliensis pollen	non-standardized pollen allergenic extract
triticum aestivum pollen	non-standardized pollen allergenic extract
tropicamide	anticholinergic

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Active Moiety Name	PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
trospium	muscarinic antagonist
trout, unspecified	non-standardized food allergenic extract
trypan blue	diagnostic dye
trypan blue free acid	diagnostic dye
tsuga canadensis pollen	non-standardized pollen allergenic extract
tsuga caroliniana pollen	non-standardized pollen allergenic extract
tsuga heterophylla pollen	non-standardized pollen allergenic extract
tuberculin purified protein derivative	skin test antigen
tuberculin purified protein derivative	tuberculosis skin test
tuna, unspecified	non-standardized food allergenic extract
turkey	non-standardized food allergenic extract
turnip	non-standardized food allergenic extract
turnip	non-standardized plant allergenic extract
turnip greens	non-standardized food allergenic extract
turnip greens	non-standardized plant allergenic extract
typha angustifolia pollen	non-standardized pollen allergenic extract
typha latifolia pollen	non-standardized pollen allergenic extract
ulipristal	progesterone agonist/antagonist
ulmus alata pollen	non-standardized pollen allergenic extract
ulmus americana pollen	non-standardized pollen allergenic extract
ulmus crassifolia pollen	non-standardized pollen allergenic extract
ulmus glabra pollen	non-standardized pollen allergenic extract
ulmus parvifolia pollen	non-standardized pollen allergenic extract
ulmus pumila pollen	non-standardized pollen allergenic extract
ulmus rubra pollen	non-standardized pollen allergenic extract
umeclidinium	anticholinergic

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights  Indications and Usage heading if a drug is a member of an EPC [see 21 CFR  201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document.  For more information about how FDA determines the EPC Text Phrase, see the 2009  "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
unoprostone	prostaglandin analog
urea c-13	H. pylori diagnostic
urochloa mutica pollen	non-standardized pollen allergenic extract
urofollitropin	gonadotropin
urokinase	thrombolytic agent
ursodiol	bile acid
urtica dioica pollen	non-standardized pollen allergenic extract
ustilago avenae	non-standardized fungal allergenic extract
ustilago bullata	non-standardized fungal allergenic extract
ustilago cynodontis	non-standardized fungal allergenic extract
ustilago hordei	non-standardized fungal allergenic extract
ustilago maydis	non-standardized fungal allergenic extract
ustilago nuda hordei	non-standardized fungal allergenic extract
ustilago tritici	non-standardized fungal allergenic extract
vaccinia virus strain new york city board of health live antigen	live vaccinia virus vaccine
valacyclovir	nucleoside analog HSV DNA polymerase inhibitor / VZV DNA polymerase inhibitor
valacyclovir	nucleoside analog HSV DNA polymerase inhibitor / VZV DNA polymerase inhibitor
valacyclovir	nucleoside analog HSV DNA polymerase inhibitor / VZV DNA polymerase inhibitor
valganciclovir	nucleoside analog CMV DNA polymerase inhibitor
valproic acid	antiepileptic drug (AED)
valproic acid	mood stabilizer
valsartan	angiotensin II receptor blocker
vancomycin	glycopeptide antibacterial
vandetanib	kinase inhibitor
vanilla	non-standardized food allergenic extract

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Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
vardenafil	phosphodiesterase-5 (PDE-5) inhibitor
varenicline	nicotinic receptor partial agonist
varicella-zoster virus strain oka/merck live antigen	live attenuated herpes zoster virus vaccine
varicella-zoster virus strain oka/merck live antigen	live attenuated Varicella zoster virus vaccine
veal	non-standardized food allergenic extract
vecuronium	nondepolarizing neuromuscular blocker
vedolizumab	integrin receptor antagonist
velaglucerase alfa	hydrolytic lysozomal glucocerebroside-specific enzyme
velvetleaf huckleberry	non-standardized food allergenic extract
velvetleaf huckleberry	non-standardized plant allergenic extract
vemurafenib	kinase inhibitor
venison	non-standardized food allergenic extract
venlafaxine	serotonin and norepinephrine reuptake inhibitor (SNRI)
venus clam, unspecified	non-standardized food allergenic extract
verapamil	nondihydropyridine calcium channel blocker
verteporfin	photoenhancer
verticillium albo-atrum	non-standardized fungal allergenic extract
vespula germanica venom protein	standardized insect venom protein allergenic extract
vespula maculifrons venom protein	standardized insect venom protein allergenic extract
vespula pensylvanica venom protein	standardized insect venom protein allergenic extract
vespula squamosa venom protein	standardized insect venom protein allergenic extract
vespula vulgaris venom protein	standardized insect venom protein allergenic extract
viburnum sieboldii pollen	non-standardized pollen allergenic extract
vicia sativa pollen	non-standardized pollen allergenic extract

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR  201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
vigabatrin	antiepileptic drug (AED)
vilanterol	beta-2 adrenergic agonist
vinblastine	vinca alkaloid
vincristine	vinca alkaloid
vinorelbine	vinca alkaloid
vismodegib	hedgehog pathway inhibitor
vitamin a	vitamin A
vitis girdiana pollen	non-standardized pollen allergenic extract
vitis vinifera pollen	non-standardized pollen allergenic extract
von willebrand factor human	human blood coagulation factor
vorapaxar	protease-activated receptor-1 (PAR-1) antagonist
voriconazole	azole antifungal
vorinostat	histone deacetylase (HDAC) inhibitor
vulpia myuros pollen	non-standardized pollen allergenic extract
warfarin	vitamin K antagonist
watercress	non-standardized food allergenic extract
watercress	non-standardized plant allergenic extract
watermelon	non-standardized food allergenic extract
western diamondback rattlesnake (crotalus atrox) immune fab antivenin (ovine)	antivenin
wheat	non-standardized food allergenic extract
wheat gluten	non-standardized food allergenic extract
whey	non-standardized food allergenic extract
white catfish	non-standardized food allergenic extract
white crappie	non-standardized food allergenic extract

	FDA Established Pharmacologic Class (EPC) Text Phrase
	PLR regulations require that the following statement is included in the Highlights
	Indications and Usage heading if a drug is a member of an EPC [see 21 CFR
Active Moiety Name	201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each
Active Molety Name	listed active moiety, the associated FDA EPC text phrase is included in this document.
	For more information about how FDA determines the EPC Text Phrase, see the 2009
	"Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for
	Use in the Highlights" MAPP 7400.13.
whitefish, unspecified	non-standardized food allergenic extract
wine grape	non-standardized food allergenic extract
wine grape	non-standardized plant allergenic extract
xanthium spinosum pollen	non-standardized pollen allergenic extract
xanthium strumarium pollen	non-standardized pollen allergenic extract
xanthium strumarium var. canadense pollen	non-standardized pollen allergenic extract
xenon xe-127	radioactive diagnostic agent
xenon xe-133	radioactive diagnostic agent
xerophyllum tenax pollen	non-standardized pollen allergenic extract
yeast	non-standardized food allergenic extract
yeast	non-standardized fungal allergenic extract
yellow fever virus strain 17d-204 live antigen	attenuated yellow fever virus vaccine
yellow perch	non-standardized food allergenic extract
yellowfin tuna	non-standardized food allergenic extract
yersinia pestis 195/p antigen (formaldehyde	inactivated Yersinia pestis vaccine
inactivated)	· · · · · · · · · · · · · · · · · · ·
zafirlukast	leukotriene receptor antagonist (LTRA)
zaleplon	GABA A agonist
zanamivir	influenza neuraminidase inhibitor (NAI)
zea mays pollen	non-standardized pollen allergenic extract
ziconotide	N-type calcium channel antagonist
zidovudine	HIV nucleoside analog reverse transcriptase inhibitors (HIV NRTI)
zileuton	5-lipoxygenase inhibitor
zinc cation	copper absorption inhibitor

Active Moiety Name	FDA Established Pharmacologic Class (EPC) Text Phrase  PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: "(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)]." For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.
zinc dibutyldithiocarbamate	standardized chemical allergen
ziprasidone	atypical antipsychotic
zizania palustris pollen	non-standardized pollen allergenic extract
zoledronic acid	bisphosphonate
zoledronic acid anhydrous	bisphosphonate
zolmitriptan	serotonin 5-HT1B/1D receptor agonist (triptan)
zolpidem	GABA A agonist
zonisamide	antiepileptic drug (AED)
zucchini	non-standardized food allergenic extract